SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF ORANGE - COMPLEX JUSTICE CENTER
DEPARTMENT CX-102

THE PEOPLE OF THE STATE OF CALIFORNIA, acting by and through acting Santa Clara County Counsel Orry P. Korb and Orange County District Attorney Tony Rackauckas,	
Plaintiff,	
vs.	NO. 2014-00725287
PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; JOHNSON & JOHNSON JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS, INC.; ENDO PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; and ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.; and DOES 1 through 100, inclusive,	
Defendants.	

TRIAL PROCEEDINGS
BEFORE THE HON. PETER J. WILSON, JUDGE PRESIDING
REPORTER'S TRANSCRIPT OF REMOTE PROCEEDINGS

Tuesday, May 18, 2021

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(And other appearances as may be found on Clerk's Minute Order.)

I-N-D-E-X

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BY MS. LUCAS		2377			
BY MR. STAMPFL		2385			
BY MR. FORAN		2386			
A. LEMBKE	2393				

E-X-H-I-B-I-T-S

NO.		I.D.	EVD.
P-CA-000921	Entire Dashboard		2392
P-CA-001367			2455
DEF-CA-102015			2333
DEF-CA-102016			2333
	WITHDRAWN FROM EVIDENCE		
ROA 6702	All documents admitted on 5-17-21 are now withdrawn from evidence to include the following:		2333
P-CA-000921			
JAN-CA-102005			
JAN-CA-603066			
JAN-CA-603067			
JAN-CA-603068			
JAN-CA-602964			
JAN-CA-602966			
JAN-CA-602967			
JAN-CA-602968			
JAN-CA-602969			
JAN-CA-602970			
JAN-CA-602971			
JAN-CA-602972			
DEF-CA-101976			
DEF-CA-102005			
DEF-CA-102006			
DEF-CA-100099			
DEF-CA-101954			
DEF-CA-102003			
DEF-CA-102015			
DEF-CA-102016			
DEF-CA-101952			
DEF-CA-101953			
DEF-CA-101959			
DEF-CA-101964			
DEF-CA-101977			
DEF-CA-101981			
DEF-CA-101984			
DEF-CA-102000			
DEF-CA-102001			
DEF-CA-102002			

FROM SANTA ANA, CALIFORNIA - TUESDAY, MAY 18, 2021

MORNING SESSION

9:00 A.M.

-OOO-

(The following proceedings were held via Zoom with all counsel appearing remotely:)

THE COURT: Good morning, everybody. We are back on the record. We are going to start with several procedural issues.

One item from yesterday. We discussed and I admitted the documents identified in ROA 6702. This was the document that resulted in further discussion about how to treat the IQVIA data sets and how they were to be addressed.

On taking a look at the submission, I do not think it appropriate to have admitted all of the documents. What the parties agreed was not to object to admissibility of the data sets. The agreement is reciprocal regardless of which party chooses to introduce the evidence.

It does not appear to me, looking at these documents, that these are the sorts of documents that should simply be admitted untethered to a witness. Instead, pursuant to what the parties I think intended to

agree, if a witness intends to discuss or refer to a document and the document is then admitted, there would be no objection.

My proposal, therefore, would be to withdraw the wholesale admission of these documents and instead, as and when documents are proffered that are on this list, there would be no objection.

Does any party wish to be heard on that issue?

MR. PENDELL: Your Honor, yes. I need to go back and check the transcript, but I think that I did actually offer the data through Ms. Keller is my recollection, and I think it was admitted without objection.

THE COURT: Which data, Mr. Pendell? There's a whole list of databases here.

MR. PENDELL: I'm sorry, your Honor. I was having a speaker problem. I did not hear what you said.

THE COURT: Which data are you referring to? There's a whole list of data sets.

MR. PENDELL: I apologize. It was the IQVIA data specifically.

THE COURT: There are approximately ten-plus different IQVIA data sets identified here. Is it your recollection that all of these were somehow admitted through Keller's testimony?

MR. PENDELL: No, your Honor. I believe it was

three. And I can give you the specific Bates numbers, and I can go back and, like I said, check that transcript to verify that it was those three. And I can get clarification for you by this afternoon if that's okay, your Honor.

THE COURT: Let's do this in the interim, then. The blanket order that I entered yesterday which was that everything identified on 6702, ROA 6702, was admitted is withdrawn. Those documents are not admitted on a wholesale basis as listed in that document.

Documents previously admitted, of course, remain admitted. And if any witness -- if, through any witness, counsel intend to introduce any of these identified documents pursuant to this stipulation, there would be no objection and they would be admitted. But I'm not doing a blanket admission of them today.

Mr. Pendell, on the ones that you think are covered, either raise it during trial and we can address it like that or file something indicating which ones you believe Ms. Keller properly -- you moved to admit through Ms. Keller, and I'll confirm that those are indeed admitted.

MR. PENDELL: Your Honor, while we were speaking, it's been handed to me that it has been verified -- I apologize. There were actually two that went in through Ms. Keller, and they are DEF-CA-102015

and 016.

THE COURT: Both of those are in this list. And both of those, if not already formally admitted, are hereby formally admitted. 102015, 102016. Both have the DEF Bates number.

(Whereupon, Defendants' Exhibit Nos. DEF-CA-102015 and DEF-CA-102016 were received in evidence.)

(Whereupon, exhibits previously admitted as part of ROA 6702 on 5-17-21 are now withdrawn from evidence.)

marked for identification.)

THE COURT: Also a question on exhibits. ROA 6812 is the People's amended list of exhibits admitted during trial on May 3. The list purports to be documents actually admitted into evidence on May 3. But commencing on page 5, line 8, there are pages of data sets that, according to my notes and my clerk's notes, were not referred to or admitted on that date.

I need to understand why they're listed here and what the party -- what the People had in mind.

MS. FITZPATRICK: I apologize, your Honor. I'm going to have to go pull that with someone and get an answer for you either by the break or immediately after lunch.

THE COURT: It's ROA 6812, and the question

starts on page 5, line 8.

MS. FITZPATRICK: Okay.

THE COURT: From there to the end, there is a list -- many of which, just on a very quick review, seem to mirror some of those in the previous documents we just discussed, but I certainly don't have a record of them being admitted on May 3. Just take a look at that, and let's discuss again when you have a chance.

MS. FITZPATRICK: Certainly, your Honor.

THE COURT: Picking up yesterday's issues, the People's bench brief in support of admitting the data from the Orange County Health Agency report.

Are the People ready to address that issue again?

Ms. Fitzpatrick, you're on mute. Was Mr. Robinson going to cover this?

MR. ROBINSON: Your Honor, I don't know if you can hear me. I am on mute, I think.

MS. FITZPATRICK: He was, your Honor. I see him or at least see his screen.

THE COURT: Mr. Robinson, are you with us?

MR. ROBINSON: Can you hear me now, your Honor?

THE COURT: I can hear you now. Thank you.

MR. ROBINSON: Okay. Good, I'm sorry.

Really, your Honor, I'd rather not do this at this time. I think that, you know, we have -- there was

one statement by you that you're going to allow us to have this evidence come in, and I think in some ways you've changed positions.

But I think before we can really figure this all out, I'd like to move on with other witnesses and whatnot, your Honor, and then we can discuss this. Part of me doesn't really want to have to call other witnesses and whatnot. I do think what the Court said is accurate in the transcript here I read.

But I really would like to wait, your Honor, and maybe we can discuss this when there's not a potential witness here waiting to be examined.

THE COURT: We'll simply table this issue for further discussion and no rulings are made with respect to the request at this time. Before the People rest, obviously, we'll need to readdress the issue if the People wish to do so.

The admissions issue may be in a similar vein.

Do the parties want to table that issue until we don't have witnesses on deck?

MR. STAMPFL: That would be fine with the Allergan defendants, your Honor.

MR. BAKER: That's fine with the People as well.

THE COURT: Let's do that. We'll keep that on second call, so to speak, as well.

I did not have anything else of a procedural

nature before returning to the witnesses. Was there anything else from the parties' perspective we need to address before resuming witnesses testimony?

MR. BAKER: Yes, your Honor. Fred Baker for the People. Just one issue that I briefly raised yesterday to keep on your Honor's radar.

The defendants have listed roughly 45 live will-call witnesses. As your Honor can see, we're coming down towards the end of our case. And in order to facilitate our preparations for crosses, we believe it's appropriate at this point in time for the defendants to begin paring back their list so that we can actually have a real list to work off of.

THE COURT: Mr. Baker, I'll return to that issue. I'm not likely to push it until we are at the stage where the People rest so that I can appropriately tell the defendants they now know the scope of the case that they're meeting and they need to make their, at least, firmer decisions.

So that issue is duly noted, and we will return to it, but nothing that I think is the right thing to push today.

How many more days of testimony, simply approximately, are the People anticipating?

MS. FITZPATRICK: Your Honor, we anticipate that we should go through the early part of next week, Monday

or maybe into Tuesday at some point, and we will then be ready to rest our case. We have a few witnesses who are left and some depositions -- and deposition transcripts to get into evidence. So we anticipate that the defendants would be able to begin their case next week.

THE COURT: All right. Thank you.

Are the People ready with their next witness?

MS. McPHERSON: Yes, your Honor. This is Malia McPherson from the Oakland City Attorney's Office for the People. The People will call Officer Julian Bordona as our next witness. And he should be in the waiting room, if he is not currently on the screen. And I see him now.

THE COURT: Madam Clerk, would you swear the witness, please.

THE CLERK: Please raise your right hand. Mr. Bordona, please raise your right hand.

MS. McPHERSON: It looks like there's some speaker issues. He is generally pretty tech savvy. So I think if we give him a second.

THE CLERK: Where did he go?

THE WITNESS: I think I have you, ma'am. Thank you, ma'am. Apologies.

THE CLERK: No problem. Thank you. Let's see.

Do you solemnly state that the testimony you shall give in this matter now pending before this court will be the truth, the whole truth, and nothing but the

truth, so help you God?

THE WITNESS: I do.

THE CLERK: Please state your name and spell your last name for the record.

THE WITNESS: Julian Bordona, B-O-R-D-O-N-A.

THE CLERK: Thank you.

* JULIAN BORDONA *

called as a witness by and on behalf of the plaintiff, having been first duly sworn, was examined and testified as follows:

THE COURT: Good morning. Thank you.

Ms. McPherson, you may continue.

MS. McPHERSON: Thank you, your Honor.

* DIRECT EXAMINATION *

BY MS. McPHERSON:

Q And thank you, Officer Bordona, for being here this morning. Let's begin.

Are you a current employee of the City of Oakland?

A Yes.

Q In which City of Oakland department?

A The police department.

Q And what is you're current position in the Oakland Police Department?

A I'm currently a sworn peace officer assigned to the Violent Crimes Operations Center.

Q Great. And we'll get to what your work entailed in Oakland in greater detail in just a few minutes, but for now how long have you been with the Oakland Police Department?

A Approximately six and a half, almost seven years.

Q And have you testified in court before?

A Yes.

Q Approximately how many times?

A I would say anywhere between a dozen to two dozen.

Q And were all of those times for criminal matters?

A Yes.

Q And were all of those times with the Oakland Police Department?

A Yes.

Q And for purposes of this morning, is it okay if I use the term OPD to refer to the Oakland Police Department?

A Yes.

Q I'm going to turn now to ask you about your education and work history briefly.

What was your first position or job as a first responder?

A That was an EMT, ma'am.

Q And what does EMT stand for?
A Emergency medical technician.
Q Where did you attend EMT school?
A Modesto Junior College.
Q And after you graduated from EMT school, how long did you work as an EMT?
A Approximately 18 to 24 months.
Q And what did you do after that?
A I attended paramedic school.
Q And did you graduate from paramedic school?
A That would have been -- I believe it was July of 2005.
Q And was that the same year, 2005, that you received your paramedic license?
A Yes.
Q And what training is required to obtain a paramedic license?
A For that there is a classroom portion of approximately -- I believe it's 320 hours. There is a clinical portion in a hospital that is approximately 240 hours and then clinical rotations on an ambulance of anywhere between 480 to 720 hours.
Q Thank you.
And are you still a licensed paramedic?
A Yes.
Q And at a high level, please explain the

difference between an EMT and a paramedic.

A An EMT is essentially an assistant to a paramedic. Paramedics are the ones administering intervenous drugs and more invasive procedures for patient care.

Q Where did you work as a paramedic?

A Stanislaus County.

Q How long did you work as a paramedic in Stanislaus County?

A That would have been approximately 10 years, 12 including the EMT portion.

Q And I'm going to turn now just to ask some questions about your training and background work as a paramedic. In asking you questions I'm going to use the term "opioids."

Please tell the Court your understanding of that term so that we can all be on the same page when I'm using the term "opioids" in my question.

A Opioids speaking to either the illicit street drug use or also to include prescription drugs.

Q Okay. Great. And I think you answered this but just to confirm, when I use the term opioids, you'll understand that I mean both illicit and prescribed ones?

A Yes.

Q As part of your paramedic training, were you trained in identifying and responding to opioid

overdoses?

A Yes.

Q At a high level, what type of training did you receive to identify the response to opioid overdoses?

A Recognition of signs and symptoms along with what would be described as outlying factors near my patient.

Q Did you receive paramedic training to distinguish between opioid overdoses and non-opioids overdoses?

A Yes.

Q Please describe any training you received as a paramedic to identify/distinguish between different types of opioids.

A From that it would be understanding the different trade names that are used in prescribing, along with the different paraphernalia associated with illicit use.

Q As a paramedic, did you respond to opioid overdoses?

A Yes.

Q How frequently?

A I would say anywhere from five to ten calls within a month period.

Q And as a paramedic responding to calls, which types of opioids did you encounter?

A Everything from a prescription to include fentanyl, Dilaudid, things of the such, up to heroin use via intravenously or through nasal use.

Q How often as a paramedic did you have to distinguish between different types of drug overdoses to inform your response as a paramedic?

A That would be any time there was an overdose patient, be it accidental or intentional.

Q And how frequently, if you had to estimate?

A Including the accidental, I would put that anywhere from 10 to 15 in a month period.

Q And based on your training and field experience as a paramedic, what signs and symptoms would you look for as signs of an opioid overdose?

A In order to determine from head to toe, you would be looking at pupillary response, or how the pupils respond to light, whether they're equal, the size of the pupil; along with skin signs, if somebody is pale, cool to the touch, diaphoretic or what's referred to as sweaty; to include respirations, determining whether they are below the acceptable level to sustain life; along with the cognitive awareness of the patient.

Q And to confirm, those are signs and symptoms you would look for to confirm an opioid overdose; is that correct?

A Yes.

Q Based on your training and field experience as a paramedic, what other nonmedical signs would you look for in identifying an opioid overdose?

A With that, we would also expand our visualization of the patient to include the immediate scene in their area. With that, we would be looking for prescription bottles that can lead us to understanding what this person may have taken, loose pills nearby. Also any kind of illicit paraphernalia, be it pipes, syringes, lighters, spoons with residue, anything of the such.

Q What was the primary method you used in response to opioid overdoses as a paramedic?

A Would that be referring to the treatment modality?

Q Yes. Thank you.

A That would be Narcan, or what's also referred to as naloxone.

Q And I know that we have had testimony already in this case, but just so the Court understands your understanding, what is Narcan?

A In the most simple way to define it, it is an antidote for opioid overdose.

Q I'm going to transition now to asking about your career in law enforcement.

From your career as a paramedic, what was your

first position when you transitioned to law enforcement work?

A As a police officer trainee in the Oakland Academy.

Q And to confirm, did you have any transitional work from your paramedic that also incorporated law enforcement work?

A I did spend approximately four years assigned to a SWAT team in the city of Ceres as a tactical paramedic.

Q And so then you previously said you applied to be a police officer; is that correct?

A Yes.

Q And what was your first position with OPD?

A That would have been the police officer training position.

Q And was that part of the police academy?

A Yes.

Q When did you graduate from the Oakland Police Academy?

A July 3rd, 2014.

Q And what was your first sworn role with OPD?

A I would have been assigned to the patrol division.

Q And approximately how long were you assigned to the patrol division?

A That would have been approximately a year and a

half.

Q What were your primary duties as a patrol officer in the patrol division?

A Primary duties was responding to calls for service, be it generated by 911 use or flag-downs with bystanders that were saying we need help here, to include proactive patrol in areas that are determined to be problematic in our area.

Q And when you were a patrol officer, how much of your time while on duty did you spend in the Oakland community?

A Approximately 90 percent of my time.

Q And when you were out in the community, describe further what your day-to-day looked like as a patrol officer.

A Typically, it will start at the beginning of shift with a briefing, lasting anywhere from 15 to 20 minutes, describing events prior to our shift, events that were determined to be happening during our shift, and any other intelligence information that we needed to have to be able to effectively police our community. And in addition to that, also forecasting any training that would be happening either that day or the following day.

Q And I think you described the shift change.

Could you further describe what the rest of your day-to-day looked like as a patrol officer.

A From there we would obtain our vehicles which we were assigned, do our checkout, make sure we had all of our equipment, and then proceed to answer what we call call for service or anybody that has called 911 that has a scene on what we call our board or the computer system that dispatches.

From there, once we handled all the calls that were in our beat, we were able to focus on proactive policing and be able to assist our community resource officers that have identified problems in the beat to which we were assigned.

Q What was your next sworn role with OPD?

A From there, I tested and was accepted into our crime reduction team.

Q Do you still work on the crime reduction team?

A Yes, under a different name.

Q And I think you mentioned this earlier. What is that new name?

A Approximately two months ago we transitioned our name to become the Violent Crimes Operations Center.

Q And describe at a high level the activities of the Violent Crime Operations Center.

A We handle all of the enforcements related to the more violent crimes in the city. Typically any crime that results from gunfire or gang activity is what we respond to. We are the more -- boots on the ground, if

you will, for our investigations division with our investigators, who are also referred to as detectives, in order to apprehend the more violent of the criminals in the city of Oakland.

Q And if I use the acronym VCOC, will you understand that to mean the Violent Crime Operations Center?

A Yes.

Q As a member of the VCOC, how much of your time do you spend in the Oakland community?

A Anywhere from 70 to 80 percent of my time.

Q When you are out in the Oakland community, describe what your experience of day to day looks like.

A Typically, we are responding to the more violent and affected areas of Oakland due to gang activity and firearm-related crimes. We can conduct anything from plainclothes surveillance to include any kind of narcotics sales that are related to the gang activity, the firearms trafficking, along with conducting search warrant services and arrest warrant service.

Q And please describe at a high level any special or individual responsibilities you have in addition to your work in the VCOC.

A In addition, I'm also assigned to our training division. I am a member of the training cadre for first aid and CPR. I currently am the subject matter expert

for the department for medicine along with conducting in-service training, academy training for first aid, CPR. Excuse me. With that, I also offer policies and procedures that pertain to medicine, and I am also the liaison for our Narcan program.

Q Thank you. I'll turn in a minute to ask you some more questions about the Narcan program.

You described earlier that, in your paramedic training, you were trained to identify and distinguish between different types of opioids.

For any of your positions at OPD, were you also trained to identify and distinguish between different types of opioids?

A Yes.

Q And which position did you receive that training for?

A That was during the academy as a police officer trainee.

Q What type of training did you receive?

A That was identification and recognition of signs and symptoms of overdoses.

Q Did you receive any nonmedical training in the academy about identifying and distinguish between types of opioids?

A Yes.

Q And what type of nonmedical training did you

receive?

A That was identification of paraphernalia used in order to allow a subject to use illicit drugs along with the recognition and identification of the drugs themselves.

Q I'm going to turn now to background and what you've observed regarding opioids in your work in Oakland.

Based on your personal observations in the seven or so years that you've been an OPD peace officer, have you observed an impact of opioids on the Oakland community?

A Yes.

Q What have you personally observed reflecting an impact of opioids on the Oakland community?

A I've seen a substantial increase in just the paraphernalia you see on the street. Initially when I first began working as a peace officer, it was more focused into just general areas of known drug use and drug trafficking. And over the course of the last several years, I've seen it explode into affecting almost all areas of Oakland that I've encountered.

Q Please describe any problems or effects associated with opioid use that you've observed in the community.

A So one of the things that is most prolific to me

has been identifying that paraphernalia near my schools, near my churches, various places that you would not expect to see paraphernalia, especially to the degree that we have seen it.

Q And in the course of your duties as a peace officer, where have you observed these impacts of opioids on the community?

A Citywide.

Q I'm just going to break down some of those observations a little bit further.

In the course of your duties as a peace officer in Oakland, have you personally observed instances of opioid use?

A Yes.

Q What types of opioids have you observed being used?

A I have observed --

MS. LUCAS: Objection, your Honor. This witness has not been designated as an expert.

THE COURT: And what part of the question does the objection pertain to?

MS. LUCAS: The extent that he's offering his opinion on what types of opioids he's observing, then we would have an objection; to the extent he's only describing factual matters, we don't.

MR. FORAN: And if I could, your Honor, it lacks

foundation to offer testimony about what types of opioids he's observed being used.

THE COURT: The objection is partly sustained to this extent: The witness can describe what he observed and -- we'll start there. The witness can describe what he observed. Whether opinions flow from that, we'll tell from the questions and the answers.

Please proceed.

THE WITNESS: Thank you, your Honor.

One of the things I have observed has been users of opioids using a pill bottle that contains coins along with pills themselves that they will shake in order to break the pill form into a powder. From that powder, they are able to place it into a spoon and melt it down using a lighter, draw it up via syringe. I've also observed subjects injecting opioids directly into their venous system.

BY MS. McPHERSON:

Q And why do you believe you observed opioid use in those instances?

A Due to the fact that this was an area that was known for the trafficking of such, along with the signs and symptoms that followed their use.

Q And in the course of your duties as a police officer, what types of opioids specifically do you think that you've observed being used?

A I would speak to heroin along with any kind of pill form that may have been obtained.

Q And how often have you observed instances of what you believe to be opioid use in Oakland?

MS. LUCAS: Objection, your Honor; foundation and improper opinion.

THE COURT: Overruled.

You may answer.

THE WITNESS: Could you repeat the question, ma'am?

BY MS. McPHERSON:

Q Yes. Give me one second.

How often have you observed instances of what you believed to be opioid use in Oakland?

A Several times. I would put it well over two to three dozen.

Q And in the course of your duties as a peace officer in Oakland, have you observed instances of what you believe to be opioid overdoses in the community?

A Yes.

Q What have you observed personally regarding opioid overdoses in the community?

A Speaking to that, I have observed subjects falling asleep during questioning. I have observed subjects that were unconscious during time frames and situations where being unconscious is inappropriate.

Q And how often have you personally observed opioid overdoses in Oakland?

A Five to six on my own response.

Q In the course of your duties as a peace officer in Oakland, have you observed opioid use paraphernalia in the community?

A Yes.

Q What type of paraphernalia associated with opioids have you observed?

A Empty and discarded pill bottles, along with syringes, spoons. A common thing that is often missed by the layperson to be identified as such are -- the best way to describe it are, like, the tea light candles, how they come in a metal tin. Those are often given out at clean needle dispensaries in order for somebody to draw up in a more safe manner what they use. Those are often discarded along with the blue rubber tourniquets that are handed out in the same kits.

Q About how often do you observe paraphernalia associated with opioid use?

A Every day I step out of the police department.

Q In the past seven or so years in the course of your duties as a peace officer, have you observed any changes or trends in opioid prevalence in the community?

MS. LUCAS: Objection, your Honor; improper opinion, foundation.

THE COURT: Sustained as to opinion.

MS. McPHERSON: May I be heard briefly, your Honor?

THE COURT: Yes.

MS. McPHERSON: I believe I just asked him what he had personally observed regarding changes and trends, a yes-or-no question. And he should be able to answer based on his percipient witness testimony.

THE COURT: You're not asking him for a yes or no, are you?

MS. McPHERSON: That was the first question I asked him.

THE COURT: Just a moment.

The objection to the question as framed is sustained. You may rephrase your question.

MS. McPHERSON: Thank you, your Honor.

BY MS. McPHERSON:

Q Officer Bordona, in the course of your duties as a peace officer, have you observed any changes or trends in opioid impacts in the community?

MS. LUCAS: Same objection.

THE COURT: The objection is overruled.

BY MS. McPHERSON:

Q I can repeat the question if that would be helpful as well.

A Yes, ma'am.

Q In the course of your duties as a peace officer, have you observed any changes or trends in opioid impacts in the community?

A Yes.

Q And what have you observed regarding changes or trends in opioid impacts in the community?

MS. LUCAS: Same objection.

THE COURT: Overruled.

THE WITNESS: What I've observed has been an explosion, if you will, of the amount of paraphernalia that is observed throughout the city.

BY MS. McPHERSON:

Q Does the prevalence of opioids in the community affect your work as a peace officer?

A Yes.

Q And how does the prevalence of opioids in the community affect your work as a peace officer?

A It affects it on the level of officer safety due to our requirement during searches to place hands in the pockets. Oftentimes this is where needles are kept, be it capped or uncapped, along with simple things as tripping and falling in the street. If there's an uncapped needle in the gutter, which there typically is, that can become an officer safety issue as well.

Q Thank you. I'm going to turn now to the Narcan program that you mentioned earlier. I believe you

mentioned -- said the name -- can you please tell the Court the name of the program?

A Oakland Police Department Narcan Program.

Q And who created this program?

A It was a cocreation between myself and Josh Luftig, a PA that is at Highland Hospital -- or Alameda County Hospital.

Q And you mentioned that Josh Luftig is a PA. Could you describe further who Josh Luftig is?

A He is a PA that operates out of their emergency department and is also the coordinator for the California Bridge program.

Q What is the California Bridge program?

A The California Bridge program is a treatment modality and resource for those wishing to stop the opioid addiction that they have.

Q And you said that you cocreated the program. What was your role in creating the program specifically?

A Mine was the liaison, if you will, from the Oakland Police Department along with making sure that the program itself fit within the policies and procedures of our department.

Q And at a high level, please explain the OPD Narcan program.

A The OPD Narcan program placed Narcan into the hands of the officers on the streets along with the

refresher training on its use and identification of opioid overdoses.

Q Which part of the OPD Narcan program has already been implemented?

A We have implemented Phase I that is currently operational and the -- what I can refer to as a pilot program for Phase II.

Q And briefly what is Phase I?

A Phase I is the Narcan being in the hands of the officers on the street along with the training for recognition of overdose and treatment.

Q And -- excuse me. Briefly, what is Phase II?

A Phase II is the proactive deployment of Narcan into the -- in the hands of individuals that are determined to be, quote, at risk.

Q Which part of the OPD Narcan program have you not yet implemented?

A Phase III.

Q And what is Phase III?

A Phase III would be what could be described as a leave-behind program. To further explain, if an officer were to respond to an opioid overdose and either they or other first responders used Narcan, that officer would be instructing the -- basically the cohabitants of where this patient lived on recognition of signs and symptoms along with leaving Narcan with them should this person

overdose again in the future.

Q And from your perspective as one of the creators of this program, why was it important for officers to be trained and able to carry Narcan?

A For me, it was knowing that it can have an effect and actually be out there saving lives. To me, it is no different than an officer carrying a tourniquet. Gunshot wounds don't want to happen or don't need to happen, just like overdoses don't need to happen. But they are easily fixed.

Q And when did you begin this program?

A That would have been end of October 2019.

MS. McPHERSON: And, your Honor, I'm going to pull up a document now. And I believe Evan is our tech person right now.

Evan, if you could please pull up exhibit labeled P-CA-001737. And --

MS. LUCAS: Your Honor, the defense has an objection to this document.

THE COURT: What's the objection?

MS. LUCAS: Lacks foundation. It contains hearsay and double hearsay. It's irrelevant to Phase I. And 352 as well as improper opinion.

THE COURT: Just a moment, please.

MS. McPHERSON: Your Honor, let me know if you would like me to respond at this time.

THE COURT: Just a moment, please.

I have the document on my screen. It has not yet sought to be admitted. At the moment, all that has happened is the witness has been referred to the document.

The objection to the document simply being referred to is overruled. You may continue your objections on a question-by-question basis as appropriate. Let's see what the questions are.

Counsel may continue.

MS. McPHERSON: Thank you, your Honor.

BY MS. McPHERSON:

Q Officer Bordona, you have the document in front of you; is that correct?

A Yes.

Q And you've had an opportunity to look through it?

A Yes.

Q Do you recognize this document?

A Yes.

Q And what is this document?

A This is a PowerPoint utilized for training officers on the Narcan program.

Q Did you create this PowerPoint?

A Yes.

Q And what was the purpose of this PowerPoint?

A The purpose was to have a visual representation of my training. Due to my P.O.S.T. certified instructor certification, I have to teach to the different learning -- learning modalities that an adult can use, one of these being visual. And that speaks to the visual side.

Q So your training as an OPD officer has had additional components of materials beyond what was on this slide?

A Yes.

Q And were these materials -- this PowerPoint document what was, in fact, used to train officers in the OPD Narcan program?

A Yes.

Q Is this document maintained in OPD's records?

A Yes.

Q And where is this document maintained?

A This is currently accessible from all sworn members through the PowerDMS program.

Q And just for the Court, what is the PowerDMS program?

A That is an archive of all of the training -- the training PowerPoints, along with policies, procedures, department general orders, chief's special orders. Pretty much any piece of paperwork that flows through the department that can be referred to as training or policy

is located in this database.

Q And this is the version that you used, the Version 2.4 that's labeled on the first slide here, is this the version that you used to train OPD officers in the Narcan program?

A Yes.

MS. McPHERSON: Your Honor, I'd move to have this Exhibit P-CA-001737 admitted into evidence.

MS. LUCAS: Objection, your Honor. There is no foundation that this is, in fact, a business record underneath the evidence code. It also contains hearsay, double hearsay, and there's no foundation for many parts or actually all of the parts of the contents of the document.

THE COURT: What's the purpose of moving its admission?

MS. McPHERSON: Your Honor, we understand your position in this case on the narrow business records exception. To save the time of going slide by slide and laying a foundation for each slide, I would admit it for a nonhearsay purpose. We are admitting it for -- to prove what OPD officers were, in fact, trained with for the OPD Narcan program.

The defendants have also put at issue in this case whether the jurisdictions have taken any effort in response to the opioid crisis. So we're putting it in

evidence to -- as well as in to showing what the jurisdictions, specifically Oakland, did in response to the opioid problems in the community.

MS. LUCAS: I also have a relevance objection, your Honor, to Phase I.

MS. McPHERSON: And, your Honor, this is directly relevant to Phase I. It goes to the scope of the problem. We are not admitting it to show what resources or further actions would be needed, which would be a Phase II issue. We're admitting it to show the harm and the existence of the public nuisance in the city of Oakland.

MS. LUCAS: May I be heard briefly, your Honor?

THE COURT: Yes.

MS. LUCAS: To the extent the relevance is the scope of the problem, that directly implicates our hearsay objection because the only parts of this presentation that could possibly be relevant to the scope of the problem contains hearsay for which there's also no foundation.

THE COURT: Ms. McPherson, if you are not admitting it for the truth of its contents, then it proves only that the Oakland Police Department has a Narcan training program. The officer has testified to that. What is the relevance of this document beyond that?

MS. McPHERSON: Your Honor, I believe it also -- that Officer Bordona testified that this is what officers were, in fact, trained on. So it shows the materials that officers were trained on. It lays foundation for later testimony as well regarding what officers observed and what Officer Bordona has observed in the city of Oakland and provides foundation for that.

And I think just the extent of the training materials are relevant to the scope of the problem and what officers were trained in.

THE COURT: I don't think the People can have it both ways. If it is not offered for the truth of its contents, all it establishes is that Oakland Police Department has a Narcan training program, to which the officer has already testified.

The objections to the admission of the document itself are sustained.

MS. McPHERSON: Thank you, your Honor.

Evan, you may take the document down.

BY MS. McPHERSON:

Q Officer Bordona, in whole, when do you train Oakland police officers to use Narcan?

A Sorry. Could you repeat the question?

Q Yes. In whole, when do you train OPD officers to use Narcan?

A When they have recognized or determined to have

recognized an opioid overdose.

Q Are OPD officers trained to use Narcan to respond to all types of drug overdoses?

A No.

Q Are OPD officers trained to use Narcan to revive someone who has overdosed exclusively on methamphetamines?

A No.

Q Are OPD officers in this program trained to use Narcan as a treatment, a diagnostic tool, or both?

A Typically, it can be used for both.

Q And can you explain that further?

A Due to the fact that Narcan in and of itself is utilized and only works on opioid overdoses, if you have a patient that is unconscious, unresponsive, with decreased respirations and you give them Narcan, when they wake up, you have, in fact, determined that an opioid is what they overdosed on.

Q What categories of OPD officers were trained using the materials that we saw but were not admitted?

A Any officer that leaves the police station in the capacity of being on the street in patrol.

Q And do you have an estimate of how many employees in OPD received Narcan training?

A Anywhere between 250 to 300.

Q And why do you think, in your role as the

creator of the program, there was a need to train that many OPD employees in Narcan administration?

A Due to the fact, through my experience in talking with other officers, if you are, in fact, a police officer that works in the city of Oakland, you will see an overdose at some point.

Q Who above you in the chain of command supported the OPD Narcan program?

A Everyone from the chief at the time down.

Q And you mentioned the chief. Describe any role the chief played in authorizing the OPD Narcan program.

A That would have been in July of 2019. I was conducting an -- a meeting, if you will, with our chief and our top brass -- basically, assistant chief, deputy chiefs -- explaining my vision for this program and the Oakland Police Department. From there the chief, Anne Kirkpatrick, tasked me as being the person in charge for this program.

Q Where was the initial Narcan for the program obtained?

A That was through a donation from Highland Hospital and the California Bridge program.

Q Did you obtain Narcan from other sources for the program?

A Yes.

Q And I will get to that. I'm going to again pull

up the document. Just at this point pulling it up, not seeking to admit it.

So, Evan, please pull up P-CA-001087.

MS. LUCAS: Your Honor, we also have objections to this document on foundation, hearsay, double hearsay, relevance to Phase I --

THE COURT: Ms. Lucas, I do not need to hear from you on a document unless and until anyone seeks to admit it. Please hold your objections until we -- I have some idea why the document is being proffered. That a document is being referred to is not in itself objectionable except in rare cases. If it's a rare case, by all means. But please otherwise hold your objection until I understand what the questions are.

What is this document number again, please?

MS. McPHERSON: This is document -- Exhibit Number P-CA-001087.

THE COURT: Please proceed.

MS. McPHERSON: Thank you.

BY MS. McPHERSON:

Q Officer Bordona, do you have the document in front of you?

A Yes.

Q Do you recognize this document?

A Yes.

Q What is this document?

A This is my -- the grant application to obtain further restock and supply of Narcan.

Q And I think you started to answer there in saying that this was your document. Did you create this grant application?

A I coauthored, if you will, with Josh Luftig.

Q Did you submit this grant application?

A Yes.

Q And did you submit this grant application on behalf of the Oakland Police Department?

A Yes.

Q What approval did you receive to submit this grant application?

A This would have been approval through the -- my immediate chain of command on the training section side of my chain of command.

Q And to submit this document on behalf of the Oakland Police Department, did it need to represent the views of the Oakland Police Department?

A Yes.

MS. McPHERSON: Your Honor, move to have this document admitted into evidence.

MS. LUCAS: Your Honor, we object to the foundation of this document, and, in particular, those first four paragraphs contain hearsay, double hearsay for which he has no foundation, and improper opinion. It's

also irrelevant to Phase I. He's already testified that the Oakland Police Department has a Narcan program.

THE COURT: For what purpose is the document being proffered?

MS. McPHERSON: For the -- for several nonhearsay purposes.

First, proving the police department applied for a Narcan grant, which is separate than just having a Narcan program as Officer Bordona had previously testified.

It also represents the position of the Oakland Police Department. It's not being admitted for the truth of that but just admitted as to the position of the Oakland Police Department when it applied for the Narcan and with respect to what it viewed as the need to respond to the scope of the opioid crisis.

Officer Bordona is here testifying as a fact witness, and this document is a document that he can authenticate and has authenticated and laid foundation for regarding the views of the Oakland Police Department.

MS. LUCAS: May I be heard briefly?

THE COURT: Yes.

MS. LUCAS: There's been no testimony about where this data came from. In fact, at his deposition, he testified that somebody else gave it to him. And to the extent this is being offered for Oakland police's

understanding of the issue, that is, in fact, for the truth.

MS. McPHERSON: Your Honor, may I respond to that?

THE COURT: Just a moment, please.

Ms. McPherson, what's not clear to me is the same confusion, if you will, between what the People say that they are proffering this for and what the People, in fact, mean to proffer this for.

If it is not being offered for the truth of its contents, what is its relevance beyond establishing that the City of -- the Oakland Police Department approved -- applied for and received a grant to support the provision of Narcan, to which the officer has already testified? What does the document add to that testimony if it's not admitted for the truth of its contents?

MS. McPHERSON: Your Honor, it also speaks to the need for Narcan at the time, the amount of Narcan that the department is seeking. I don't think that the specifics at issue -- we're not seeking to admit this document for the part that Ms. Lucas has concerns with, but it simply goes to what defendants have repeatedly put at issue in this case, which is that the jurisdictions themselves do not have a belief that there's an opioid problem and have not responded as if there's an opioid problem. And this document goes beyond simply that they

applied for a grant, and it goes to the views as written down and formally submitted in a grant application of the Oakland Police Department.

I believe the views of the Oakland Police Department are different than the truth of the matter of those views.

THE COURT: The objection to the admission of the document is sustained. When the witness is cross-examined on this issue or the earlier issue of the Narcan training, if there is something in the cross-examination that makes the contents somehow additionally relevant, the issue of the admission of the documents may be revisited.

But at the moment, since the proffer is that they are not offered for the truth of their contents, they have no other relevance. And both because the document itself contains hearsay and because, under a 352 analysis, admitting the entire document to establish a fact to which the witness has already testified is more likely to be confusing rather than helpful, the objection is sustained. You may revisit the question on cross if that becomes appropriate.

Please proceed.

MS. McPHERSON: Thank you, your Honor.

And, Evan, if could you zoom in. I want to look at the first sentence of the document.

BY MS. McPHERSON:

Q I will read the first sentence. And, Officer Bordona, you can make sure that I am reading it correctly.

It says, "The Oakland Police Department (OPD) is an urban police force in Oakland, California, in Alameda County, a community highly impacted by the opioid crisis."

Do you see that sentence?

A Yes.

MS. LUCAS: Objection, your Honor. The objection was sustained.

THE COURT: Assuming the witness confirms that he can see that or heard what you read, what's the question, counsel?

MS. McPHERSON: I am going to ask him to -- I didn't understand your ruling to mean that I could not ask any further documents about this exhibit, even if it was not admitted into evidence.

THE COURT: That's not a response to my question.

What is your question based upon what you have just read to the witness?

MS. McPHERSON: Yes, your Honor, and apologies. My question is going to be whether he wrote it, lay a foundation for that sentence, and whether that is his

belief as well.

MS. LUCAS: In which case, that's improper opinion.

THE COURT: In the interest of time, the Court interposes its own objection. I thought the witness expressly testified that he believes that there is an opioid issue in Oakland that he has been addressing for years.

What does this add other than an opportunity for objection?

MS. McPHERSON: I can move on, your Honor.

THE COURT: Please.

MS. McPHERSON: Thank you.

And, Evan, you may take the document down. Thank you.

BY MS. McPHERSON:

Q Officer Bordona, approximately -- approximately how many times did OPD officers use Narcan in the initial months of the program?

A From the beginning of November until the end of the year -- so December 31st -- there were 20 deployments or uses of Narcan.

Q Was this level of Narcan usage surprising to you?

A It was.

Q Did you track whether Narcan administrations

were successful?

A Yes.

Q And are you able to approximate what percentage of OPD Narcan administration were successful since the beginning of the program?

A 16 reversals.

Q And what percentage, would you approximate?

A Approximately 80 percent.

Q And what is your understanding of the term "successful" here?

A Meaning a subject --

THE COURT: Ms. McPherson, how is this relevant to Phase I?

MS. McPHERSON: Your Honor, I can move on. The People believe that the scope of the problem and the success rate through the Narcan reversal show the existence of the scope of the problems with respect to opioid overdoses in the community.

THE COURT: 20 uses is relevant, and I have no issue with that. Whether or not Narcan was successful, I do not understand how that's in any way relevant to Phase I as opposed to Phase II.

Please move on.

MS. McPHERSON: Thank you, your Honor.

BY MS. McPHERSON:

Q Officer Bordona, please explain whether the OPD

Narcan program is the only Narcan program in Oakland.

A It is not.

Q What other programs deploy Narcan?

A All ambulances have Narcan available for their paramedics to use, along with the Oakland Fire Department, or OFD, also has Narcan available for their paramedics to utilize.

Q And describe the typical circumstance when you, as an OPD officer, would respond to an opioid overdose rather than those other entities or departments.

A Common times will be what is referred to as a flag-down, which refers to a citizen or subject that observes a black-and-white police car in the vicinity waves their hands to get our attention and then directs us to a subject that is either unconscious or nonresponsive.

Q During the COVID-19 pandemic, has the OPD Narcan program continued?

A It has with -- with less ferocity, if you will.

Q Can you explain that further, what you mean?

A With that, when the pandemic first impacted our department, we scaled back our call activity to minimize contact outside of essential calls for service.

Q And have you continued to track Narcan use during the pandemic?

A To the best of my ability, yes.

Q Describe any continued impact of opioids in your day-to-day work since the OPD Narcan program began.

A To speak to the impact to my work, it has made it difficult due to the fact that I am not -- I have other duties as well. This is a -- for lack of a better term, a secondary assignment from my primary.

Q And what do you see now when it comes to the impact of opioids on the community during the pandemic?

MS. LUCAS: Objection; relevance and improper opinion.

THE COURT: Overruled.

You may answer.

THE WITNESS: Could you restate the question, ma'am.

BY MS. McPHERSON:

Q Of course. What do you see now when it comes to the impact of opioids on the community during the pandemic?

A From the best I can gather, it has not changed it. There may be an increase. However, I'm unable to assess that directly.

MS. McPHERSON: Thank you, Officer Bordona. No further questions on direct at this time.

THE COURT: Thank you, Ms. McPherson.

Cross-examination of the officer?

MS. LUCAS: Thank you, your Honor.

* CROSS-EXAMINATION *

BY MS. LUCAS:

Q Officer Bordona, my name is Amy Lucas. I represent Janssen and Johnson & Johnson. I think we can make this fairly short.

You talked about your experiences treating people who had overdosed, and you talked a little bit about clues that you saw at the scene. But even if you see clues at the scene, there's no way for you to say with any certainty what substance someone overdosed on, correct?

A Correct.

Q Even if you recognize signs and symptoms of an opioid overdose, you can't decipher what specific opioid caused it, can you?

A No, I would say not specifically.

Q And you also can't tell if that person took another illicit or prescription drug besides opioids in addition, correct?

MS. McPHERSON: Objection; foundation.

THE COURT: Overruled.

THE WITNESS: I'm sorry, ma'am. Could you repeat the question?

BY MS. LUCAS:

Q Sure. You also can't tell if the person took another illicit or prescription drug besides opioids,

correct?

A That would depend on signs and symptoms that are presented by the patient. It could be difficult, but again, I wouldn't be able to fully assess without doing a direct assessment myself.

Q But even if you're doing a direct assessment and you see signs of an opioid overdose, you don't know if they took something else besides opioids too, correct?

A That's correct.

Q And you're also aware that non-opioid drugs, like methamphetamine, are being laced with opioid-like illicit fentanyl in Oakland, correct?

MS. McPHERSON: Objection; foundation.

THE COURT: You may answer if you can.

THE WITNESS: I am aware that there are combinations often taken.

BY MS. LUCAS:

Q And those are combinations of things like methamphetamine and cocaine mixed with illicit fentanyl, correct?

A That could be.

Q And, in fact, sometimes there are situations where a person doesn't even know what they've overdosed on, correct?

A That could be possible, yes.

Q And you don't know whether overdoses in Oakland

are related to prescription or illicit opioids, correct?

MS. McPHERSON: Objection; foundation and misstates his prior testimony.

THE COURT: Overruled.

THE WITNESS: I'm sorry, ma'am. Could you repeat.

BY MS. LUCAS:

Q I said you don't know whether overdoses in Oakland are related to prescription opioids or illicit opioids, correct?

A Not unless I am physically on scene for that specific call.

Q Right. And even when you are on scene for a specific all and even if you see clues, you can't say with certainty what substance somebody overdosed on, correct?

A Not typically.

Q Officer Bordona, you'd agree that there's a large population of methamphetamine users in Oakland, right?

MS. McPHERSON: Objection; foundation.

THE COURT: Sustained as to foundation.

BY MS. LUCAS:

Q Officer Bordona, you've seen in your -- in the course of your duties that there are individuals in Oakland who use methamphetamine, correct?

A Yes.

Q Okay. And you have noted that, in the course of your duties, that you formed the belief that Oakland has a large population of methamphetamine users?

A I do believe there are a large population of methamphetamine users.

Q And in your experience as an officer for Oakland Police Department, the biggest problem that you've observed in Oakland involved drugs that are available for use in intravenous form, correct?

MS. McPHERSON: Objection; vague.

THE COURT: Overruled.

THE WITNESS: I'm sorry, ma'am. Could you repeat.

BY MS. LUCAS:

Q Yes. In your experience as an officer for Oakland Police Department, the biggest problem that you observed in Oakland involved problems that are drugs that are available for intravenous use, correct?

A Yes, that's correct.

Q And those drugs include heroin and illicit fentanyl, correct?

A I could not speak to that.

Q You were deposed in this action, correct?

A Yes.

Q And you told the truth at your deposition?

A Yes.

MS. McPHERSON: Objection. We will see where we get, but he was deposed as the Oakland PMK, not in his personal capacity.

MS. LUCAS: Stan, could you put up Officer Bordona's deposition page 66, lines 2 through 11.

"QUESTION: Can you identify any drug that you think is most affecting Oakland?

"ANSWER: Any drug that is available for use in intravenous form.

"QUESTION: And which drugs with those be?

"ANSWER: Heroin is probably what I would say is the most well known. Fentanyl is available to be used that way. You have got any form of -- any form of an illicit drug that is able to be melted down into a liquid and drawn up into a syringe."

BY MS. LUCAS:

Q Now, I want to talk briefly about --

You can take that down. Thank you.

-- about the Narcan program that you just told the Court about at Oakland Police Department. I think you said that the groundwork for the program began somewhere around September of 2019, correct?

A The -- the idea and the -- the meeting with the chiefs happened in, I believe it was, June or July, and

the official groundwork, being my offering of the trainings for, yes, that would speak to right around September.

Q Okay. And then it launched around end of October, November 2019, correct?

A Yes.

Q Now, Narcan can be used for any opioid, whether it's an illicit opioid like heroin or fentanyl or a prescription opioid, right?

A Yes.

Q And it can also be used if someone overdoses on a non-opioid, like methamphetamine that's been laced with an opioid like illicit fentanyl, correct?

MS. McPHERSON: Objection; relevance.

THE COURT: Ms. Lucas, what's the -- what is this relevant to?

MS. LUCAS: It's relevant to the fact that Narcan is being used on people who don't even know that they have injected opioids.

THE COURT: And that has not been established because...

MS. LUCAS: What do you mean? I'm not following your question.

THE COURT: You have already asked the officer whether he can tell with certainty precisely what was used. The officer has already testified that Narcan, in

a sense, has a reverse confirmation. If they suspect an opioid, they will use it. If it works, it was an opioid.

Is there something else that you are trying to establish?

MS. LUCAS: Only that the program is also used, in fact, on those individuals.

THE COURT: Please proceed.

BY MS. LUCAS:

Q Do you need the question again, Officer Bordona?

A Yes, ma'am. Thank you.

Q Sure. Narcan can also be used if someone overdoses on a non-opioid, like methamphetamine that's been laced with illicit fentanyl, correct?

A Reversing the fentanyl ingestion, yes.

Q Correct. So that means Narcan can be used on people who unknowingly use opioids, correct?

A Referred to as an accidental overdose? Yes.

Q And those accidental overdoses would be that they had no idea that they had ingested an opioid, correct?

MS. McPHERSON: Objection; speculation.

THE COURT: Ms. Lucas, asked and answered. Please move on.

BY MS. LUCAS:

Q Now, Officer Bordona, you are responsible for keeping the statistics regarding the number of times that

Oakland PD has used Narcan, right?

A Yes.

Q And when officers at Oakland PD administer Narcan, they're required to log the information and also contact you to report it, correct?

A Yes.

Q But the officers are not required to document what type of opioid they believed was in the person's system that caused the overdose, correct?

MS. McPHERSON: Objection; beyond the scope of direct.

THE COURT: Overruled.

THE WITNESS: Just to make sure I answer correctly, ma'am, could you repeat.

BY MS. LUCAS:

Q Of course. Officers are not required to document what type of opioid they believed was in the person's system that caused the overdose, correct?

A They are not required.

Q And as of the day that you were deposed in this action, Oakland PD's Narcan supply was sufficient, correct?

MS. McPHERSON: Objection. Phase I.

THE COURT: Sustained.

BY MS. LUCAS:

Q For Narcan, correct?

A Yes.
Q And if you need more, you can get it, correct?
A Yes.
MS. LUCAS: Thank you for your time, Officer Bordona. No further questions. My colleagues may have some for you.
THE COURT: Thank you, Ms. Lucas.
Any other defendant with questions for the officer?
MR. STAMPFL: Yes, your Honor. Karl Stampfl for the Allergan defendants, please.
* CROSS-EXAMINATION *
BY MR. STAMPFL:
Q Officer, my name is Karl Stampfl. I represent the Allergan defendants in this case.
Now, you testified on direct about the opioid overdoses to which you've responded. I just want to make sure. Among those overdoses, you have certainly seen indications that the individual was shooting heroin, correct?
A Under certain circumstances, yes.
Q And you've certainly seen indications that the person was using illicit fentanyl, correct?
A That would be difficult to determine. It would depend on what was seen with the subject.
Q Let me ask you this. My client's opioid is

called Kadian.

Am I correct that you can't confirm that a single one of the individuals who overdosed tested positive for Kadian?

A That was -- that would not speak to my level of expertise. That would be our criminalistics lab.

Q So you would not be able to confirm that a single one of those overdoses involves Kadian, correct?

A I would not.

MR. STAMPFL: Thank you. That's all I have.

THE COURT: Thank you, Mr. Stampfl.

Any other defendants with questions?

MR. FORAN: Yes. Very briefly, your Honor.

* CROSS-EXAMINATION *

BY MR. FORAN:

Q Good morning, Officer Bordona.

A Hello, sir.

Q Now, in addition to your responsibilities with respect to the Narcan program, you have also worked on criminal investigations on behalf of the OPD, correct?

A Yes.

Q And during your time at the OPD, you've worked on over a hundred investigations; is that right?

A I believe so, yes.

MS. McPHERSON: Objection; beyond the scope of direct.

THE COURT: Mr. Foran, I assume this is going to become relevant at some point?

MR. FORAN: Yes. This is going to be relevant in terms of the number that involved opioids and the number of those that are relevant to prescription opioids.

THE COURT: Please move on, Mr. Foran. Ask your questions. Let's see where this goes.

MR. FORAN: Oh. Thank you, your Honor.

BY MR. FORAN:

Q Of those hundred investigations, about half involved drugs; is that correct?

A I believe so.

Q And of those investigations, about 20 to 25 involved opioids?

A Is that coming from a statistic? I wouldn't be able to speak to that myself without looking at the numbers.

Q Well, that was your testimony when you were deposed in February of last year, correct?

A Then yes.

Q And of those 20 to 25 that involved opioids, you don't know how many involved prescription opioids; is that correct?

A Yes.

MS. McPHERSON: Same objection. Beyond the

scope of direct as to criminal investigations.

THE COURT: The objection as beyond the scope is overruled. But, Mr. Foran, please avoid repetition of testimony already given.

MR. FORAN: Yes, your Honor. That's all I have on that point. Just one more quick issue.

BY MR. FORAN:

Q Officer, you are aware of the existence of counterfeit prescription opioid pills in Oakland, correct?

A I'm aware they are out there.

Q Yeah. You're aware that there are pills that are manufactured to replicate prescription opioid pills, correct?

A Yes, I'm aware.

Q And sometimes they are dyed the same color as prescription opioid pills, correct?

MS. McPHERSON: Objection; foundation.

THE COURT: Overruled.

THE WITNESS: Can you ask one more time, sir.

BY MR. FORAN:

Q Sure. Yes, yes. So sometimes these counterfeit pills are dyed to be a color that would make them look like the kind of pill that might come from a -- that might be a prescription opioid; is that right?

A I'm aware of this, yes.

Q And sometimes they are even stamped with a number to indicate dosage or make them look genuine?

THE COURT: Mr. Foran, the question is are they made to look exactly like an original. Is there a reason to ask five questions on so straightforward a subject?

MR. FORAN: No, your Honor. Thank you.

I have no further questions.

THE COURT: Thank you, Mr. Foran.

Does any other defendant have questions for the officer?

MR. JAMES: I thank Officer Bordona for his service to his community and have no questions for him.

THE COURT: Thank you, Mr. James.

Reexamination?

MS. McPHERSON: Just briefly a few questions, your Honor.

* REDIRECT EXAMINATION *

BY MS. McPHERSON:

Q Officer Bordona, from a police officer perspective in Oakland, does it matter what type of opioid causes an overdose?

A No, ma'am.

Q And why not?

A It doesn't change our treatment.

MS. McPHERSON: Thank you, your Honor. No further questions.

THE COURT: May the officer be excused?

MS. McPHERSON: From the People's perspective, yes.

MS. LUCAS: From the defense perspective, yes.

And thank you, Officer Bordona, for your time and service.

THE WITNESS: Thank you, ma'am.

THE COURT: Officer Bordona, you may stand down, sir, and you are excused. Thank you very much for your time today.

THE WITNESS: Thank you, your Honor.

THE COURT: We will take the morning break at this time. We are adjourned until 20 to 11:00. Thank you.

(A brief recess is taken.)

THE COURT: All right. We are back on the record.

Mr. Pendell has confirmed that there is one additional document that was previously admitted into evidence that appears on ROA 6702. That is document P-0921. And to the extent it has not been previously formally admitted, that document is admitted.

The People are calling as their next witness Dr. Anna Lembke.

Ms. Fitzpatrick?

MS. LAURENDEAU: Excuse me for one moment, your

Honor. Amy Laurendeau. May I just make a quick point on Exhibit 921. I just think there's an ambiguity on the record that needs to be cleared up on Exhibit 921.

During Mr. Robinson's examination of Dr. Quick, the Court exhibit -- or the Court admitted Exhibit 921 as a one-page document, a printout screenshot, essentially, of the California opioid overdose dashboard. And I believe 921 has also been admitted as the dashboard itself and the underlying data. So I do think there's an ambiguity there that should be clarified for the record.

THE COURT: Thank you. Pursuant to the stipulation contained in ROA 6702 -- well, let me get more clarification from Mr. Pendell.

Mr. Pendell, with respect to this document 0921, without going back through my notes, precisely what portion was identified when the document was first admitted and what about the dashboard is being admitted other than the page that was identified at the time of the witness's testimony?

MR. PENDELL: Well, your Honor, it was my understanding the entire dashboard was in. And Dr. Stafford relied on the dashboard extensively and used far more than just a single page from that dashboard.

THE COURT: That's my recollection as well. So my assumption is that at this time the entire dashboard, which has the Exhibit Number 0921, is coming in.

Ms. Laurendeau, is there an issue with what the parties intended under ROA 6702?

MS. LAURENDEAU: There is not, your Honor. We don't object to the admissibility of the dashboard in its entirety. This is really just more of a clerical issue I was raising. At page 635 of the consolidated trial transcript when Mr. Robinson was examining Dr. Quick, he asked to admit and the Court admitted what was referred to as Exhibit 921.

And the Court stated, "I admitted the one page that had been shown on the screen to the doctor." That is Exhibit 921 as admitted.

THE COURT: All right. Thank you. I appreciate the clarification. What is admitted today, then, is the P-CA-0921 which constitutes the entire California Opioid Overdose Surveillance Dashboard as identified in ROA 6702. Thank you.

P-CA-000921 in its entirety was received in evidence.)

MR. ROBINSON: Thank you.

THE COURT: Ms. Fitzpatrick?

MS. FITZPATRICK: Thank you, your Honor. We call Dr. Anna Lembke, who was here. I saw her.

THE COURT: Good afternoon. Are you with us?

THE WITNESS: Yes, I am. Can you not see me?

THE COURT: Good morning. I can now.

Madam Clerk, would you swear the witness, please.

THE CLERK: Please raise your right hand.

Do you solemnly state that the testimony you shall give today in this matter now pending before this Court will be the truth, the whole truth, and nothing but the truth, so help you God?

THE WITNESS: Yes, I do.

* ANNA LEMBKE, MD *

called as a witness by and on behalf of the plaintiff, having been first duly sworn, was examined and testified as follows:

THE CLERK: Please state your full name and spell your last name for the record.

THE WITNESS: Anna Lembke, L-E-M-B-K-E.

THE CLERK: Thank you.

* DIRECT EXAMINATION *

BY MS. FITZPATRICK:

Q Good morning, Dr. Lembke. Can you tell the Court your current position?

A I am professor of psychiatry and addiction medicine at Stanford University School of Medicine. I am medical director of addiction medicine, chief of the Addiction Medicine Dual Diagnosis Clinic, and program director for our addiction medicine fellowship.

Q And, Dr. Lembke, we worked together to prepare some slides for this case, correct?

A That is correct.

Q If we can pull up the first slide.

And for ease, Dr. Lembke, we're going to rely on the slides to go through some of your qualifications in this matter.

Can you tell the Court what your education is?

A I did my undergraduate at Yale University. Then I got my medical degree from Stanford University. I did two years of pathology, a year of internal medicine at Highland Hospital in Oakland. And I did a psychiatry residency here at Stanford and a fellowship in mood disorders before joining the faculty here at Stanford.

Q And when did you join the faculty at Stanford?

A It was 2003.

Q And are you licensed to practice medicine?

A Yes, I am.

Q And from when?

A I'm licensed to practice medicine from -- 1995 was the year I graduated.

Q In what areas do you practice?

A I'm a psychiatrist. I also have a courtesy appointment in team medicine. And my area of focus is addiction as well as deprescribing, helping people who are dependent on chemicals like opioids to slowly and

safely get off of them.

Q Are you board-certified in any areas?

A I am. I am board-certified in psychiatry and neurology and also in addiction medicine.

Q And as part of your appointment at Stanford, do you teach medical students?

A I do.

Q And when did you begin to teach medical students at Stanford University?

A Well, I began actually when I was a -- a medical student myself as a TA, and then essentially continued on in that capacity, joining the faculty, which is the classic three-legged stool type of appointment, part clinical work, part scholarly work, and part teaching. And I've been teaching medical students and residents for the past 25 years.

Q In what subjects do you teach medical students and residents?

A I teach many different aspects related to mental health. I teach about addiction in all its various forms. I have taught extensively on the opioid epidemic, including the problem of misleading messaging that has influenced prescribing in medicine. I teach on the overlap between addiction, dependence, and pain. I teach about the neuroscience of addiction.

Q And looking at this slide, Dr. Lembke, and your

related experience, can you tell the Court what diplomate and adviser to the American Board of Addiction Medicine is?

A Diplomate simply means that I'm board-certified in that discipline, and I have specialized training. I sat for an exam and passed that exam. Adviser means that I sat on various committees of the American Board of Addiction Medicine in a senior leadership role.

Q Is that the same for the diplomate of the American Board of Psychiatry and Neurology?

A A diplomate of the American Board of Psychiatry and Neurology means I have specialty training in psychiatry and neurology. And I sat for the exam, I passed the exam, and I'm board-certified.

Q And looking at the next one, chief of addiction medicine, dual diagnosis clinic, and medical director, department of psychiatry at Stanford University, what is the dual diagnosis clinic?

A Dual diagnosis is a term used to identify individuals who struggle with substance use disorders and other addictions as well as a co-occurring mental health disorder. It also increasingly has come to mean individuals who struggle with some kind of chemical dependency or chemical addiction as well as chronic pain.

So our clinic is devoted to serving those patients who struggle with mental -- with multiple mental

health issues, substance use issues, chemical dependency, and also, increasingly, chronic pain.

Q And what are your responsibilities as the chief of addiction medicine in the dual diagnosis clinic?

A I'm responsible in some sense for all the patients that come through our clinic. I'm responsible for hiring and mentoring young faculty, for teaching residents, medical students, visiting scholars, for ensuring that the administration of the clinic and the oversight of the clinic is done in a safe and conscientious way consistent with medical standards.

So it's both an important clinical service role and an important teaching/mentoring/administrative leadership role.

Q And you're a medical director for the deputy of psychiatry. Is that a separate appointment at Stanford?

A I'm sorry. I'm medical director for addiction medicine within the department of psychiatry. It's a special designation acknowledging my expertise in addiction medicine and my leadership skills in this arena developing services for patients who get their care at Stanford Health services. It's become an increasingly important priority for Stanford to create these services because of the opioid epidemic.

Q And as part of your experience at Stanford University, do you -- have you done studies and research

into addiction caused by opioids?

A Yes, I have.

Q And, specifically, have you done research and studies into addiction caused by prescription opioids?

A Yes, I have.

Q And have you taught medical students and residents on issues related to opioid addiction?

A Yes, I have.

Q And how long have you been doing that?

A I've been doing that for about a decade.

Q And in addition to your role as teacher, you also maintain, I think you said, a clinical practice; is that right?

A My clinical practice is under the auspices of Stanford University School of Medicine. This is not a private clinical practice the way that those words might imply. I'm on the faculty at Stanford. I'm a paid employee of Stanford University. I'm on their university faculty. And part of my role is to provide clinical services.

Q And are part of the clinical services that you provide at Stanford University related to those who suffer from opioid use disorder?

A That is correct.

Q Let me go back to your teaching. I talked a little bit about your teaching at Stanford University.

Do you also teach those outside of Stanford University on issues related to opioid addiction?

A Yes, I do. I've given many lectures to medical schools and universities all around the country on topics related to opioid addiction and the opioid epidemic, including the misleading messaging that is in question here today.

Q And I was just about to ask you have you taught -- outside of Stanford University, have you taught about the pharmaceutical opioid industry's marketing and promotion of opioids?

A Yes, I have.

Q And have you taught on that topic in relationship to the pharmaceutical opioid industry's marketing of opioids and the opioid epidemic?

A Yes, I have. I've taught that in multiple different contexts here at Stanford, in business school, in law school, medical school, undergraduate classes. I've also been invited to Duke University, Johns Hopkins University, to many other universities to discuss this topic.

Q And have you done some research and teaching on the pharmaceutical opioid industry's partnership with or financial support for organizations that have influence on how medicine is practiced?

A Yes, I have.

Q And have you taught that both in Stanford and outside of Stanford?

A Yes, I have.

Q And when you've been teaching on this topic, do you also include your firsthand experience with the pharmaceutical opioid industry's marketing and promotion of opioids?

A Yes, I do. I am of the generation that was the primary target and recipient of the messaging. And so I do have firsthand, lived experience of how those messages were received and how they impacted medical care.

Q Can you tell the Court a little bit about your firsthand experience with the pharmaceutical opioid industry's marketing and promotion of opioids?

A Yes, I can.

Early in my career after completing my training, I was mandated by the state board of -- the Medical Board of California in 2001 to attend an all-day, mandatory seminar on the treatment of pain. I was mandated to do that in order to keep my license, as were all other practicing physicians in the state of California.

I remember being surprised that I was being mandated to go to a continuing medical education course that was outside of psychiatry and mental health. That was, in my experience, unprecedented. And at that course the messages were that there is an epidemic of,

quote-unquote, undertreated pain in the United States, that essentially we physicians were responsible for the epidemic of undertreated pain and that the reason for our responsibility had to do with our fear of prescribing opioids and our, quote-unquote, opioidphobia.

Then the majority of the day consisted of lectures on how to start opioids in patients with pain, which opioids to use, how to titrate them, that they were effective in treatment of chronic pain and many other pain states, and that as long as we physicians were prescribing them to patients in pain, it was very unlikely that the patients would get addicted.

And that messaging continued -- I would just add, because it's very important for 2001, that we were also taught that pain is the fifth vital sign so that we were required to ask every patient whether or not they were experiencing pain, whether or not there were any outward visible manifestations of pain in that patient, or whether or not the patient had sought out medical care expressly for pain treatment.

And those messages were continued throughout the entire last two decades.

Q And were you --

MR. BRODY: Your Honor, excuse me. Steve Brody for Janssen.

Move to strike the last answer due to lack of

foundation. And the question was about firsthand experience with the industry's marketing and promotion, and Dr. Lembke described a California Medical Board meeting that she attended.

THE COURT: Just a moment.

The objection is overruled.

BY MS. FITZPATRICK:

Q Dr. Lembke, in addition to the 2001 meeting that you just described, did you continue to have firsthand experience in receiving marketing and promotional messages concerning opioids from the pharmaceutical opioid industry through your career?

A Not in the last year or so.

Q Prior to -- I'm asking after the single seminar we talked about, did you continue after that to see marketing and promotional messages in your own personal career?

A Yes. I continued to see those same marketing and promotional messages throughout the first decade of the 2000s and I think, really, well into the decade between 2010 and 2020.

Q And in addition to your own personal experience in seeing and receiving those messages, have you done research and teaching on the pharmaceutical opioid industry's continuing impact on generations of doctors?

MR. KABA: Objection; vague as to "the

pharmaceutical opioid industry," your Honor.

THE COURT: Overruled.

THE WITNESS: Yes. I have continued to teach on the impact of the misleading messaging of the pharmaceutical opioid industry. And I do define that concept in my report.

BY MS. FITZPATRICK:

Q And have you also taught on the pharmaceutical opioid industry's publications in the peer-reviewed medical literature and how that has influenced physicians' opioid prescribing practices?

A Yes, I have.

Q Have you testified before Congress, Dr. Lembke?

A Yes, I have.

Q And when did you testify before Congress?

A I don't recall the exact date. I would have to look at my CV.

Q Can you tell us what you testified about?

A Yes. This was the -- I testified multiple times having to do with the impact of the flooding of society with prescription opioids as a causative element in the current opioid epidemic.

I've testified on ways that I think the government can help redress these harms, for example, by supporting more education for medical students, residents, and physicians on the nature of the

interrelationship between opioid dependence, opioid addiction, and chronic pain, including the creation of addiction medicine in fellowships.

I've testified multiple times on the need to create a better workforce to target the problem of opioid addiction and the opioid epidemic and to use academic detailing as opposed to pharma-funded messaging in order to essentially reeducate physicians to reverse the miseducation they've been receiving for the last 20 years.

Q And in addition to your testimony before Congress, I think you mentioned to me a couple minutes ago that you taught at Duke University or have lectured at Duke University; is that correct?

A Yes.

Q Do you remember when that was?

A I believe that was last year.

Q And can you tell us what you lectured on at Duke University?

A That was a class specifically on the ways that the pharmaceutical industry's packaging and messaging of the evidence can influence the ways that doctors prescribe opioids.

Q And who invited you to speak at that Global Health Institute at Duke University?

A That was the director of the course.

Q And who was the target audience? Who was in the audience for that lecture?

A They were Duke undergraduates.

Q And I want to turn to your clinical experience in a second, but all of the teaching that we've just been talking about and your testimony before Congress and the like, was that all done separate and apart from your work as an expert here on behalf of the People of the State of California?

A Yes. That's been done separate.

Q But was it all on topics that are related to your expert opinion and your testimony here today?

A Much of it is related, yes.

Q Let's go back to your clinical practice. Can you describe for the Court what your current clinical practice is comprised of?

A Our clinic now sees patients with all manner of addiction. And these are people who are addicted to drugs and alcohol, including prescription drugs, as well as people who have what we call process addiction. These are addictions to things that are not drugs, like gambling, pornography, video games.

Increasingly, our clinic has also had to fill in the gap to treat patients who have become physiologically dependent on opioids through a prescription but do not meet strict criteria for an opioid use disorder or opioid

addiction but nonetheless need professional support tapering down or off of opioids. These are the individuals that I think have really fallen through the cracks in terms of our efforts in the last five years or so to help people harmed by the opioid epidemic.

And by that I mean that we have a growing number of individuals who seek out our clinical care to help them lower their opioid doses or get off of opioids. These are individuals who are on very high doses of opioids, many of them for decades through a doctor's prescription, and have become physiologically dependent to the point that, even though the opioids are not helping their pain and, in fact, harming them, they are unable to taper the opioids because of neuroadaptation and extreme symptoms of withdrawal.

So we work with these individuals to slowly and incrementally taper them down on their doses and, when we can, to get them completely off of opioids.

Q Now, we're going to go into some of those concepts of dependence and addiction a little bit later, but going back to your clinical practice, can you estimate the number of patients you've treated for conditions related to OUD, or opioid use disorder, or dependence on opioids?

A I've treated thousands of patients with opioid addiction.

Q Are most of those patients from the vicinity around Stanford University?

A Most of them are from the vicinity, but we have patients who come from very far away, from the -- you know, the Central Valley, from the Sierras. With the increasing use of telehealth since COVID and quarantine, we are now seeing patients who live in Southern California because they're able to see us virtually.

Q Okay. And while you're working with the patients that you've described that either have OUD or dependence on opioids to address those issues, do you also work in developing treatment plans for their pain conditions as well?

A Yes. We very much prioritize integrating pain treatment with their chemical dependency or opioid addiction treatment. We've established groups specifically for the growing cohort of patients that we have who struggle with severe chronic pain.

We have a cognitive behavioral therapy group for patients with chronic pain. These are individuals in our clinic who are being treated for opioid dependence or opioid addiction who have chronic pain and need treatment for that. So that's a psychological intervention.

We also, when appropriate, use medications like antidepressants to help patients with their chronic pain. There are some antidepressants that have been shown to

have mild benefit in helping patients with those problems.

Q Dr. Lembke, several minutes ago you used a term "deprescribing." Can you tell the Court what that means?

A There are more than 10 million Americans who take opioids every day, many of whom at very -- many of whom have done so for years and decades, some at extremely high doses.

And those individuals are not benefiting and are being harmed and, in fact, are at high risk for accidental overdose and addiction with those doses yet cannot get off. So they come to our clinic voluntarily or are referred by their prescribing doctors for help with tapering down and off of opioids.

Importantly, these are individuals who are not meeting the strict DSM-5 criteria for opioid use disorder, otherwise known as addiction. They are physically dependent. They have always taken their opioids as prescribed.

Q Dr. Lembke, do you continue to treat individuals with OUD and dependence to prescription opioids today?

A Yes. It's the bulk of the practice that we do. Probably about 50 percent of our patients struggle with opioid addiction or opioid dependence.

Q And when did you first start treating individuals suffering from OUD, opioid use disorder, or

dependence on opioids?

A In the early 2000s, around 2002, 2003, I started seeing patients -- sorry. That's my phone. I'll turn it off later.

I started seeing patients, some of whom were coming in saying that they struggled with opioid dependence or opioid misuse or opioid use disorder.

I also had a patient around 2004-2005 who died of an opioid overdose. I was treating her for something else. According to her husband, she had been taking her opioids exactly as prescribed by her doctor. And so, in that sense, saying that she died of an opioid overdose is really a misnomer because she did not overdose. She was taking her medications as prescribed.

I remember in the early days I had a mother I was treating for depression who lost her son to methadone who had been prescribed methadone for pain and was taking it as prescribed.

So it was -- it really began at least to come to my attention around 2003-2004. I think it's important to point out, though, that I was in a position to observe the harm from opioids much earlier than other physicians because of the nature of my work.

MR. KABA: I am going to object and move to strike everything after "in the early 2000s, around 2002, 2003" as both a narrative and incorporating hearsay.

MS. FEINSTEIN: Join in that objection, your Honor.

THE COURT: Just a moment. The question was answered after -- or by the sentence, "I started seeing patients, some of whom were coming in saying that they struggled with opioid dependence or opioid misuse or opioid use disorder." Everything after that was nonresponsive to the question and is stricken.

BY MS. FITZPATRICK:

Q Doctor, moving on, do you prescribe opioids for pain?

A I do not prescribe opioids for pain, no.

Q Do you prescribe opioids for the treatment of OUD or dependence on opioids?

A Yes, I prescribe the opioid buprenorphine for the treatment of opioid use disorder.

Q And can you explain to the Court why you would write a prescription for an opioid for the treatment of OUD or opioid dependence?

A Buprenorphine is evidence-based treatment for opioid use disorder. And so in practicing evidence-based medicine, I use that tool in appropriate patients for the treatment of opioid use disorder/opioid addiction.

Q And you just used the term "evidence-based treatment" or "evidence-based medicine" in that answer.

Can you explain what that is to the Court?

A So evidence-based medicine is the grounding of our practice of medicine in scientific evidence. We all strive to practice evidence-based medicine, and I do so myself.

Q And what is the evidence that you're referring to there?

A There are multiple placebo-controlled trials across decades and continents, showing that opioid agonist therapy, like buprenorphine, in the treatment of opioid addiction is effective. And so I base my practice on that experience and on that -- I should say on that -- on that literature, on that evidence.

Q And does the use of buprenorphine to treat OUD or dependence on opioids raise any safety concerns for those patients?

A Yes, of course. An opioid is an opioid is an opioid. And people can get addicted to the opioid buprenorphine. They can misuse it. In rare instances they can overdose on it. It needs to be very carefully considered, carefully monitored, used very judiciously. It's a dangerous medicine.

Q Why do you use it then?

A I use it as harm-reduction strategy in individuals who essentially have brains that are fundamentally changed by exposure to opioids. And to understand that, it's really necessary to understand the

neuroscience behind how prolonged exposure to an opioid can cause neuroadaptive changes and in some instances are irreversible.

So patients to whom we give opioids to treat opioid use disorder, although on the face of it counterintuitive, is the way that we allow them to reestablish baseline homeostasis of the brain so that they're not constantly craving opioids, and that they can reengage in other recovery work, reengage with their families, reengage with their professional lives, and just generally pursue a life worth living.

Q And we are going to get into the details of the neuroscience that you just referenced there, but let me ask you a couple of more questions about your background first.

In addition to the positions that you described, do you also have a position at Stanford at the department of anesthesiology and pain medicine?

A Yes. I have a courtesy appointment in pain and anesthesia at Stanford.

Q And what is a courtesy appointment?

A Courtesy appointment is recognition of faculty contributions in different dimensions -- clinical service, teaching, scholarly work -- to a department outside of the department in which an individual has their primary appointment. So my primary appointment is

in psychiatry, but I have a courtesy appointment in pain anesthesia.

Q And do you consult with your colleagues at Stanford about treating patients who are taking prescription opioids for pain?

A Yes, on a regular basis. For many years I actually went once a week to the pain clinic and was embedded with my pain colleagues there on helping them tackle this problem of patients coming in dependent, addicted, patients with chronic pain.

And I continue to do that work primarily now located here in our building in psychiatry but also lots of what we call curbside consults on inpatients. So there's lots of collaboration and communication between myself and my pain colleagues.

Q Why is it necessary to collaborate between people like you who deal with those who are suffering from addiction or OUD or dependence and those who are managing pain?

A As a result of the opioid epidemic, pain treatment and opioid addiction treatment have become inextricably intertwined.

Q Have you, in preparation for the work that you've done both at Stanford outside of this courtroom and in this courtroom, looked at the body of medical and scientific literature that is related to OUD and

dependence on opioids?

A Yes. I have been following that literature for 15 to 20 years.

Q And --

Move to the next one, Jon.

And have you personally contributed to that body of literature?

A Yes, I have.

Q Can you tell the Court about the book that you have published on that topic?

A So I wrote this book published by Johns Hopkins University Press in 2016 called Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop.

The title, Drug Dealer, MD, is intentionally provocative because my goal was to really communicate to my colleagues within medicine as well as persons outside the practice of medicine how it was that a whole generation of doctors were duped into overprescribing opioids for minor and chronic pain conditions, leading to the opioid epidemic.

Q And was that book an extension of both the research and teaching you had done on some of those topics prior to 2016?

A Yes, it was.

Q And how did you go about doing the research for

that book?

A I read the medical literature. I did interviews with multiple stakeholders inside of medicine, patients and providers alike. I synthesized all of that information, including my own personal experience, of the misleading messaging, and I wrote a book trying to genuinely understand how it was that well-educated and well-intentioned prescribers were engaging in care that was actually harming patients.

Q Did you publish that book -- or write and publish that book before you were retained as an expert for any government entity in opioid litigation?

A I had no contact with lawyers regarding material in this book prior to writing or publishing this book in 2016.

Q And can you tell us some of the topics that you covered in that book that are pertinent to the testimony you're here to offer today?

A I emphasize in the book that the opioid epidemic is a complex and multifactorial phenomenon, that there are many -- many individuals who are culpable, including physicians like myself; including patients who lied to their doctors about how they were using medicine; including the regulatory bodies that were meant to ensure standards of care, like the Federation of State Medical Boards, the Joint Commission, the FDA.

And I also implicate the opioid pharmaceutical industry for the myths that they propagated under the guise of science that essentially duped doctors into believing that opioid prescribing in the way that it was being encouraged was evidence-based when, in fact, there was not evidence to support that kind of prescribing.

Q And, Doctor, we're going to come back to some of those messages and some of that evidence in relation to these defendants, but let me just move through your qualifications.

The BRAVO protocol, what is that?

A So about five years ago, shortly around the time that the 2016 CDC guidelines came out urging doctors to prescribe fewer opioids; to prescribe more judiciously; to not use opioids first line for pain; to, when using opioids, use the lowest dose for the shortest duration.

What happened was that many doctors went running scared and were refusing then to treat these patients, leaving us with de facto opioid refugees, patients with chronic pain who had been on opioids for a long period of time now wandering clinic to clinic trying to find somebody to help them.

So the BRAVO protocol was designed specifically to educate doctors about, number one, the importance of helping these patients and not abandoning them because of medicolegal concerns, and then specifically giving them a

compassionate patient-centered approach to how to taper opioid-dependent chronic pain patients to lower doses.

So this is a protocol to educate physicians specifically for that population of chronic pain patients physically dependent on opioids for whom a taper is indicated.

Q Thank you, Doctor.

In addition to -- we've talked about your clinical practice; we've talked about your teaching.

Have you ever been interviewed on camera about the opioid epidemic?

A Yes, I have. I was recently interviewed on the HBO documentary called The Crime of the Century, and there have been other instances.

Q Now, let me go back to some of your experience in treating patients. When did you begin to treat patients with substance use disorders generally?

A When I first began my practice of psychiatry, I was not interested in treating patients with addiction. It's not something that I had received much, if any, education on in medical school or even residency. I did not consider addiction at that time to be something within the purview of medical treatment.

And it was really only as I began my practice, my early career practice in 2000-2001, that I recognized that my patients were not getting better in large part

because I was ignoring their substance use problems.

So I decided to reeducate myself on that front and ultimately shifted my practice to specialize in treatment of patients with substance use disorders and other addictions.

Q Were there any changes in the types of substances that your patients were struggling with between the early 2000s and about 2011-2012?

A Yes. So as I said before, in the early 2000s I started seeing more and more patients coming in who were addicted to prescription opioids or misusing or dependent on prescription opioids.

Q And did that continue to increase during the first decade of the 2000s?

A Yes, it did.

Q And has that remained steady or continued to increase in the second decade of the 2000s?

A It continued to increase. And now, as I said, our clinic is probably about 50 percent of these legacy pain patients who need help with either opioid dependence or opioid use disorder, all of whom began with a prescription opioid for the treatment of pain.

Q And what do you mean by a legacy pain patient?

A This is a controversial term, but essentially what it refers to is individuals who have been adversely impacted by the overprescribing of opioids for chronic

pain, and now we have created this generation of chronic pain patients who are also dependent on or addicted to opioids. So it's a -- they're a legacy of the paradigm shift in medicine that led to overprescribing.

Q And in formulating your opinions in this case on the causes of the prescription opioid crisis, have you relied on published medical literature?

A Yes, I have.

Q And how have you gone about researching or selecting published medical literature for your opinions?

A I've monitored the major academic databases -- PubMed, MEDLINE, Google Scholar -- to keep up on papers that are written regarding opioids, chronic pain, overdose, death, whatever is out there. I have intentionally tried to look at this from all angles.

I specifically tried to look for studies showing evidence that opioids are effective in the treatment of chronic pain. And I have not been able to find those studies, but I have looked hard for those.

I have also looked hard for studies showing that addiction is rare in patients who are prescribed opioids for the treatment of chronic pain, and I have been unable to find those studies as well.

Q And in addition to the published literature, did you also look at government data and government publications as part of your research in this case?

A What do you mean by government data or government publications?

Q Things that are published by the United States, the California governments concerning opioids and opioid use?

A Yes. So I kept up on the latest publications from the CDC, for example.

Q And have you also looked -- let me ask you, were those the same types of information that you looked at prior to becoming a retained expert in opioid litigation for your research and publications concerning opioid use, opioid use disorder and the causes of them?

A Yes.

Q And did you apply any different standards to the kind of research that you did on government publications and medical and scientific literature in this case than you did in the research you have done prior to being retained as an expert?

A No.

Q And in this case, in addition to that type of information, did you look at the defendants' own documents?

A Yes, I did.

Q Okay. And did you specifically look at documents that were produced by the four defendant families in this case?

A Yes, I did.

Q Okay. And can you tell me how you went about selecting documents from the defendants that you relied on for your opinions that are specific to the report you generated in this case?

A Yes. So I was approached in 2017 by Don Arbitblit from Lieff Cabraser Heimann & Bernstein asking me if I was willing to be involved in federal opioid litigation. This was after the publication of my book.

And I initially expressed reservation about that. I hadn't done that type of work before. I wanted to be certain that my involvement would be pursuant to the truth of the matter and not to some other end. And I was reassured about the desire to explore the truth in this case.

So in my work with Lieff Cabraser Heimann & Bernstein in the MDL litigation, I was given documents by Don and his team to review, and I reviewed those documents. I then asked for additional documents as I felt I needed them as I went along in this case.

Q And what was the process of requesting and being given access to additional documents from the defendants in this case?

A Well, for example, I might review a document that they gave to me, and I would say to them, "Well, how was this document actually used? You know, who

actually -- who was the audience for this document?" Or the document might reference an article, and then I would go look up that article and try to see whether or not what the document actually purported to do with that article was what that article actually showed.

Q And how did you satisfy yourself that you had seen the relevant documents from the defendants that you needed in order to properly reach your opinions in this case?

A After reviewing multiple documents, there were recurring themes that kept coming up again and again. And based on saturation of those themes, I felt I had seen an adequate number of documents to form an opinion.

Q Just briefly outline the methodology that you used to gather the information, synthesize it, and generate your report in this case.

A Yeah. My opinion is based on all of the medical literature that I had reviewed. It is based on my review of the documents produced by the defendants in this case. It's based on 25 years of clinical experience and teaching as well as my own research that I did for the book Drug Dealer, MD.

Q And did you rely on more than just marketing studies generated by the defendants in preparing your report and reaching your opinions in this case?

A Yes.

Q And by virtue of your training, your experience, and your research, do you have a specialized knowledge in how defendants' marketing -- the prescription opioid industry's marketing of their opioids affected prescribing practices by physicians?

A I do think I have a specialized knowledge here, which is both a combination of my scholarly work, reviewing documents, reading the medical literature, as well as my experiential knowledge of having been the recipient of these marketing messages, of being in that generation of individuals trained in the late '90s and early '00s -- my generation is, in essence, the overprescribing generation.

So because I come from inside of medicine, I am a medical doctor, and I was trained in that era, I contextually understand how these marketing messages landed with prescribers.

Q Thank you, Doctor.

Okay. With that background, let me turn to some basic medical 101 -- hold that -- medical 101.

Can you start by telling us what are opioids?

A Opioids are any molecule that binds to the opioid receptor and stimulate that receptor.

Q And are there different types of opioids?

A Yes. Opioids can be naturally occurring, meaning that they begin with the opium poppy -- for

example, morphine, codeine, thebaine. They can also be what's called semisynthetic, meaning that they begin with a naturally occurring opioid from the opioid poppy and then they are altered in some way in the laboratory. And most of the Schedule II prescription opioids are semisynthetic.

And opioids can also be purely synthetic which means they do not need an opium poppy precursor and are made entirely in a laboratory, and that would include fentanyl and methadone.

Q And, Doctor, what are prescription opioids?

A Prescription opioids are opioids that can be obtained through a doctor's prescription and dispensed by a pharmacy.

Q And what is what's been called in this case illicit opioids?

A Illicit opioids are opioids that are obtained in any way that is not prescribed.

Q Do prescription opioids and illicit opioids have the same effect on the brain?

A Yes. As I said before, an opioid is an opioid. It doesn't matter if it comes in a pill bottle or you buy it on the street. Opioids work the same way on the brain.

Q And can opioids that are prescribed by a physician to treat pain conditions cause addiction and

dependence?

A Yes. Opioids that are prescribed to treat pain and used as prescribed can lead to the disease of opioid addiction.

Q Is there any reason to -- well, let me ask this: Are prescription opioids any less likely to cause addiction in those who take them than illicit opioids?

A No.

Q And we've talked earlier today in going through your qualifications about addiction and dependence.

Can you explain to the Court what addiction is.

A Addiction is a complex biopsychosocial disease that can be simply defined as the continued compulsive use of a substance despite harm to self and/or others.

Q And is that the same as opioid use disorder, or OUD?

A Yes. That is broadly speaking the same as opioid use disorder, opioid addiction. They're essentially synonyms. Opioid addiction is a more commonly understood lay term, but it is not the terminology used in DSM-5, which uses opioid use disorder instead.

Q And you also referenced earlier dependence on opioids.

Is that different from OUD?

A So dependence was singled out when the DSM-IV

went to the DSM-5. Previously, the word "opioid dependence" was used synonymously with the word "opioid addiction," but starting with the DSM-5, it was distinguished as referring exclusively to physiologic dependence, separate from opioid addiction per se.

Most individuals who become addicted to opioids are strictly dependent on opioids. But individuals can be dependent on opioids, taking them even as prescribed, without meeting the DSM-5 criteria for opioid use disorder.

So these are related phenomenon but, as of the DSM-5, separate and distinct.

Q And what is tolerance to opioids?

A Tolerance is needing more and more of an opioid to get the same analgesic response. So importantly, when we are talking about tolerance, we're not talking about habituation to side effects; we're talking about needing more opioids over time to get the same pain relief as the individual got originally.

The majority of patients, based on clinical experience, will develop tolerance to opioids if they take them every day for a period of time. What exactly that period of time is is not known and probably differs from individual to individual. But in my experience, most individuals who take an opioid every day for two to four weeks will develop some degree of tolerance, needing

more of that opioid over time to get the same effect.

I also think it's important to highlight that tolerance that develops to the analgesic effect of the opioid occurs more quickly than the tolerance that develops to the respiratory depressant effects of the opioids. So opioids decrease breathing, decrease heart rate. That's why people can die of them. They fall asleep and don't wake up again.

The central problem with opioids is that individuals will develop tolerance to their analgesic effects, and that tolerance to the analgesic effects will occur more quickly than to the respiratory depressant effects, which is why, even when taking the opioids as prescribed, patients can die from them.

Q Can you explain to the Court what happens in the brain when someone develops OUD.

A In order to understand what happens in the brain, when an individual becomes addicted to any addictive substance, it's important to talk about some of the central findings in the neuroscience in the past 75 years. And the first is that pain and pleasure are colocated.

And by that I mean that the same part of the brain that processes pain also processes pleasure, and pain and pleasure work like a balance, like a teeter-totter on a central fulcrum. So when I experience

pleasure, my balance tips to one side; when I experience pain, it tips to the other side.

The fundamental difference between the substances that are addictive, like opioids, and those that are not is how much they tip the balance to the side of pleasure. And when they do that, they release an enormous amount of dopamine in the brain for reward pathways. Dopamine is a neurotransmitter discovered in the human brain in 1950s, and it allows neurons to communicate because neurons are separated by a little gap called a synapse, and neurotransmitters are what bridge that gap for fine-tuned control of brain circuitry.

One of the most important rules governing this pleasure-pain balance is that it wants to remain level, what neuroscientists call homeostasis. And the brain will work very hard to preserve or restore neutrality.

So when I ingest an opioid, my balance tips to the side of pleasure, I get a big release of dopamine in the brain's reward pathways, and immediately the brain will put the equivalent of weight on the pain side of the balance to bring it level again.

Those weights metaphorically represent what's called neuroadaptation, the downregulation of my own dopamine transmission.

Now, the central thing to understand is that the balance will not stop here once it obtains neutrality.

It will continue to tip an equal and opposite amount to the side of pain, and that is a comedown or withdrawal. If I wait long enough after a single use, those weights come off again and the neutrality or homeostasis is restored.

To understand what happens in the brain when people become addicted is to understand what happens when that exercise, abusing that addictive opioid, occurs a second time. With repeated use, the initial effects to the pleasure side is weaker and shorter and the aftereffect to the side of pain is longer and stronger. In other words, the balance remembered, and now it needs more weight on the pain side in order to restore neutrality.

If I continue to use the opioid for days to weeks to months to years, I eventually collect so much weight on the pain side of my balance that, when I am not using, I have a balance that is chronically tipped to the side of pain. I have a different brain than the brain I started with.

This is why individuals with addiction will relapse to substance use even months after they've stopped using, even when their lives are better, they've got their jobs back, they've got their spouse back, they're walking around with a balance tipped to the side of pain.

Now, theoretically, if they wait long enough -- and I can tell you, it can take months and even years for all of that neuroadaptive weight to come off the balance -- then eventually homeostasis will again be restored.

Unfortunately, what we have learned is that, with opioid addiction, there are individuals who may never actually be able to restore homeostasis, that they may, in fact, have a broken balance such that, even after months or years of not using opioids, they continue to experience craving, insomnia, irritability, intrusive thoughts of wanting to use.

And those are the individuals to whom --

(Whereupon audio was lost by the court reporter. The Court recessed until 1:30 p.m.)

AFTERNOON SESSION

THE COURT: Good afternoon, everybody. We are back on the record.

Dr. Lembke, I remind you that you remain under oath throughout your testimony in this case. It appears that you may be on mute; so please unmute yourself.

And, Counsel, you may continue.

MS. FITZPATRICK: Thank you, your Honor.

BY MS. FITZPATRICK:

Q Dr. Lembke, when we broke, you had been testifying about certain people that you said had a broken balance. Even after months or years of not using opioids, they continued to experience cravings. And can you tell us how people who suffer from that type of OUD are treated?

A There are many different types of treatment for people with opioid addiction. It's a biopsychosocial disease; so there are biopsychosocial treatments.

But the treatment that I was speaking of before we broke was the use of opioid agonist therapies like buprenorphine and methadone maintenance in the treatment of opioid use disorder.

Q And how does that type of treatment help these individuals who, as you say, have a broken balance?

A It's instinctively counterintuitive to think

about using opioids to treat an opioid addiction, but these are opioids that have unique properties which restore a homeostatic equilibrium for these individuals, so they're not constantly living with cravings, dysphoria, and the physiologic drive to want to use opioids.

So it reasserts homeostasis and allows them to reengage with other aspects of their lives.

Q And do opioids affect people who have chronic pain or for whom -- have received prescriptions for chronic pain differently than people who take opioids for nonmedically indicated purposes?

A The fundamental process of neuroadaptation that occurs in the brain leading to addiction is also the same process that occurs in the brain of people who are given opioids for the treatment of chronic pain.

One way to think about this is that people with pain are not starting out with a level balance; they're starting out with a balance tipped slightly to the side of pain. They receive opioids which temporarily relieves their pain and reasserts a kind of homeostasis. But with repeated use over periods of time, that initial effect gets weaker and shorter. That's called tolerance. And the aftereffect gets longer and stronger.

And eventually they too end up with a pleasure-pain balance that's weighted to the side of

pain. In fact, there are individuals who are on opioids long term that develop something called opioid-induced hyperalgesia, which is just a way of saying that their pain actually gets worse as a result of long-term opioid therapy.

And if you understand neuroadaptation and the attempt of the brain to correct for homeostasis by weighting things down to the side of pain, then it becomes more intelligible how that might happen.

Q Can anyone become addicted to opioids?

A With enough exposure for a long enough period of time, anybody could become addicted to opioids.

Q Are some people more susceptible to OUD, or opioid addiction, than others?

A Yes. People come to the problem of addiction with varying degrees of vulnerability. And some are definitely more susceptible than others.

Q And what are the risk factors or the factors that make people more susceptible to OUD than others?

A Risk factors for addiction, including opioid addiction, can broadly be categorized into nature, nurture, and neighborhood.

By nature, I mean that there is an increased genetic risk for becoming addicted. If you have a biological parent or grandparent with addiction, you are more likely to get addicted even if raised outside of the

addictive home.

In terms of nurture, if you grow up in a chaotic environment and you experience early childhood trauma, epigenetic risk factors can contribute to your risk of addiction.

Finally, in terms of neighborhood, one of the most underappreciated risks of addiction is simple access to that drug. If you live in a neighborhood where drugs are sold on the street corner, you're more likely to try them and you're more likely to get addicted to them.

If you go to a doctor who is liberal with their prescription pad when it comes to controlled substances, you're more likely to be exposed to opioids and then more likely to get addicted to them.

Q Is there a reliable or foolproof way for a physician to determine who will develop OUD as a result of prescription opioids?

A No, there is not. So, in theory, because we know retrospectively what the risk factors are for developing opioid use disorder through a doctor's prescription, we should be able to predict. But the truth is that we cannot. And various opioid risk tools or screening measures have proven to be no better than chance in determining who will and will not get addicted through a doctor's prescription.

Furthermore, all of those risk factors I just

named in terms of personal history of addiction or family history of addiction or past history of trauma, those risk factors pale in comparison to the risk of dose and duration of exposure to the opioid.

Q Can a person with OUD just stop taking opioids to cure that disease?

A The majority of individuals who have severe opioid use disorder have a great difficulty stopping opioids in the face of their disease. They can do it, but they will endure a severe acute opioid withdrawal, which for some is worse than death.

And as I stated before, there is this protracted abstinence syndrome, where their pleasure-pain balance remains tipped to the side of pain, driving craving and the physiologic urge to continue to use opioids.

Q Among patients who are treated for pain with opioids, what percentage will develop OUD according to the literature?

A Reliable sources show that one in four patients will develop an opioid use disorder when being treated with opioids for chronic pain.

Q And are the risks associated with prescription opioids limited to just the people who are prescribed opioids?

A No. The people who are at risk include anybody in society who has access to opioids whether or not those

opioids were prescribed to them. One of the things I talk about in my report is not just the gateway theory of progressing from prescription opioids to illicit opioids but also what I call the tsunami effect, the flooding of our society with more prescription opioids, conferring greater access to the population as a whole and thereby increasing the risk of the entire population towards the harms of prescription opioids, including dependence, misuse, overdose, death, and addiction.

Q How does the increased supply of prescription opioids contribute to addiction and OUD rates across the population?

A The more access that an individual has to a drug, the more likely they are to try that drug and to become addicted to that drug. Opioids are furthermore unique because, different from other addictive substances, opioids have been sold and marketed as medicine.

Opioids also have a very low therapeutic index, meaning that the desired effect is very near the lethal effect. Furthermore, opioids have a very caustic and debilitating dependence and withdrawal syndrome, such that even when people try to stop, they're often unable to because of the severe symptoms of withdrawal that they experience.

Q I am going to pull up a slide that -- well, you

may. Can you explain what this slide entitled "Prescription Rates Rise, Deaths and ODs Rise"?

What is that?

A This is a slide showing that, as sales of prescription opioids increased between the years 1999 and 2010, so did treatment admissions for opioid addiction to treatment centers as well as opioid overdose-related deaths.

Q And do you have an opinion as to whether increased sale of opioids is a cause of higher rates of opioid deaths and hospitalization in the United States?

A Yes, I do. I think that the increased access through prescription is causal and can -- and is a significant contributor to the current opioid epidemic.

MS. FITZPATRICK: And can we go to Slide 5.

No. Other way. There we go.

BY MS. FITZPATRICK:

Q And is this a slide that you put together -- it's the wrong slide.

Can you explain the basis for that opinion?

A Yes, I can. So the basis for the causality opinion is the consistency of findings across not just that data point that you showed, but multiple reports and multiple data points.

Also, the strength of the association. So not merely showing a very strong association between exposure

to prescription opioids and subsequent addiction and overdose deaths but also a causal relationship between promoting opioids to doctors in a given region and increased prescribing and overdose death in that region.

Beyond consistency and strength of the association, there's also the temporal sequence that exposure to opioids precedes addiction and overdose death as well as that being a biologically plausible sequence of events. Furthermore, these opinions are not merely my opinions; there are -- this is essentially the consensus opinion in medicine now.

If you look at the National Academies of Science, Engineering, and Medicine 2017 report, it states very clearly that the promotion and marketing of opioids led to increased prescribing, led to the current opioid epidemic. Also, the Association of Schools & Programs of Public Health, a consortium of over 100 public health programs in the country, including public health programs in California, has also written an important treatise on this topic expressing the same opinion.

Q Is that the same in California?

A Yes.

Q And going back to the use of prescription opioids, can even a limited use of prescription opioids lead to OUD?

A Yes. There are data showing that even a single

prescription of an opioid in the course of medical and dental treatment can increase the risk of developing opioid use disorder within that year. Also, we know that even a brief exposure to opioids for the treatment of acute pain can, in 5 to 10 percent of individuals, lead to persistent opioid use a year to three years later. And it's important to recognize that persistent opioid use increases the risk of developing opioid addiction.

So the longer the duration of exposure to prescription opioids and the higher the dose of those prescription opioids, the greater the risk of developing addiction and of dying from those opioids.

Q Dr. Lembke, are you familiar with what's been called abuse-deterrent formulations for prescription opioids?

A Yes, I am.

Q Can you tell the Court what those are?

A Those are formulations of opioids that are crush-resistant, serving as a deterrent for crushing and snorting and crushing and injecting, two ways in which people who misuse opioids will misuse them.

Q And can taking an abuse-deterrent formulation of an opioid as prescribed by your physician lead to OUD or opioid dependence?

A The most common way that people get addicted to prescription opioids is to take them exactly as

prescribed, which is to say, if they're prescribed orally, then they take them orally and they misuse them orally and they become addicted to them orally.

Q Doctor, I want to shift a little bit, change topics to something that you called the paradigm shift. How were prescription opioids used before the 1990s in the United States?

A Prior to the 1990s doctors used opioids sparingly for surgery, severe trauma, and end of life.

Q Okay. And why was it used sparingly at that time?

A There was widespread recognition and understanding that opioids are highly dangerous drugs and highly addictive. And doctors were reluctant to give their patients an addiction to opioids.

Q And in the 1980s was there a discussion in the medical community suggesting that opioids should be used less conservatively?

A Yes. In the 1980s, there began to be recognition in the house of medicine that we were not doing a very good job treating pain. This was also the advent of the hospice movement imported from Europe advocating for more care of patients at the end of life.

There were certain individuals inside of medicine, key academic thought leaders, who began to advocate for more liberal use of opioids in the treatment

of pain in order to help people with their suffering. But there was not much data to support that. There were a few not-very-robust data points in the '80s and '90s. And so the prescribing did not appreciably increase in those decades.

Q Did there come a point in time that the prescribing started to -- the prescribing of opioids for pain started to appreciably increase?

A The late 1990s, early 2000s represents the beginning of the paradigm shift when opioid prescribing went up, quadrupling between 1989 and approximately 2012 across the United States nationally. That increase in opioids was because opioids became first-line treatment for almost any patient in pain. And doctors pushed the dose from modest and conservative low doses to very, very high doses such that it was not uncommon in that first decade and beyond to see patients on 2,000 morphine milligram equivalents daily for the treatment of their pain.

Q And when you use the term "paradigm shift," can you explain to the Court what you mean by that?

A What I mean by that is the standard of care for how to target pain in the healthcare community shifted over time. And that was accomplished through a number of ways but primarily by false and misleading messaging infiltrating the very governing bodies, professional

medical societies, and enforcement agencies that were meant to protect people from the harms of opioids.

MR. BRODY: Your Honor, I'd move to strike. Lack of foundation.

THE COURT: Just a moment.

I am mindful of the motions in limine, Ms. Fitzpatrick. You have laid an extensive foundation. You have not laid a foundation for the marketing false and misleading opinions. The foundation objection is sustained and the last answer is stricken.

You may restate the question or lay a foundation.

MS. FITZPATRICK: Thank you, your Honor.

BY MS. FITZPATRICK:

Q And, Dr. Lembke, when we were talking before about your qualifications, have you, prior to being retained as an expert by the People in this case, done independent research into whether there's a causal relationship between what you called false and misleading messages by the pharmaceutical industry and an increase in the availability of prescription opioids throughout the United States?

A Yes, I have. And that's in my book that was published in 2016.

Q And can you tell the Court how you went about doing your research for that particular proposition?

A I studied the medical literature, including government documents and what was in the lay press, attesting to the role of the opioid pharmaceutical industry in terms of their courting key opinion leaders, working together with the Federation of State Medical Boards, the relationship that they had with organizations like the Joint Commission, organizations like the Pain & Policy Study Group, publications that were put out in collaboration between the opioid pharmaceutical industry, opioid manufacturers, including defendants, and key opinion leaders who they promoted and professional medical societies, all of which resulted in drawing the medical community's attention to the promotional messages that they wanted to promote in the morass of messages that physicians have to wade through every day in order to figure out what the science is. So they essentially used that strategy to portray marketing as science.

MR. BRODY: Your Honor, I'd move to strike the last answer for lack of foundation. And also it's case-specific hearsay.

THE COURT: The answer isn't providing -- the answer did not discuss, really, the foundation, but restated -- or began to restate opinions.

The question also -- and perhaps the -- the question was misunderstood. The objection to the previous question related to an opinion being expressed

about false and misleading messaging.

That work was done to understand what the opioid -- the pharmaceutical industry might have done still does not lay a foundation or discuss what was done to investigate or form a basis for opinions about the content being false and misleading.

Ms. Fitzpatrick, the last answer is stricken. You may start again.

BY MS. FITZPATRICK:

Q Let me -- let me try it this way: Dr. Lembke, you had testified about the increase in prescriptions between 1998 and 2012. Can you explain to the Court what happened after 2012 with respect to the prescription of opioids?

A You mean in terms of the number of prescriptions?

Q I'm sorry. Yes, in terms of the number of prescriptions.

A Okay. So starting in 2012, the number of --

THE COURT: Dr. Lembke, I'm sorry to interrupt. Before I hear your opinion as to what happened, I'd like to understand the investigation, research work that you did in order to be able to express that opinion. So I need to understand what the source of your information is before I hear the opinion itself.

THE WITNESS: Thank you, your Honor. I would

like to answer that.

So I was the recipient, as were my colleagues, of these marketing messages. And I looked at the marketing messages. So I investigated them independently prior to my involvement in this litigation, and I compared those messages with the science in the medical literature in order to explore whether or not those messages represented the real data.

And the conclusion that I came to was that they were false and misleading.

Furthermore, I, in the course of writing my book Drug Dealer, MD, interviewed patients and providers about their experiences with these messages and how they interpreted them and the impact that the messages had on their prescribing. And that information, I then subjected to a qualitative analysis which led me to my current conclusions and which I do talk about in my book.

THE COURT: Ms. Fitzpatrick?

BY MS. FITZPATRICK:

Q Dr. Lembke, let's go back to your opinions concerning the increase in the use of opioids between 2012 -- or after 2012.

Can you describe to the Court whether there was an increase in opioid use after 2012?

A So I -- in 2012 prescription opioids started to go down slowly. Around that time, overdose deaths

related to heroin went up. And around 2015-2017, there was a spike in fentanyl-related overdose deaths.

Prescription opioid-related overdose deaths went down and/or plateaued during that time period between about 2012 and 2017 but did not decline -- did not considerably decline.

Q And did the increased access to prescription opioids between 1998 and 2012 lead to an increase in dependence, OUD, overdose, and death?

MR. KABA: Objection, your Honor; foundation.

THE COURT: Overruled.

THE WITNESS: The increased access to prescription opioids between 1999 and 2012 was, I believe, the biggest causative factor in the increase in opioid addiction and overdose death.

BY MS. FITZPATRICK:

Q And can you explain to the Court what the term "morphine milligram equivalent," or MME, is?

A It's a way of comparing different opioids that have different strengths, the different potencies. So using morphine as the baseline, it's a way of then comparing and contrasting the actual amount of opioids that individual was getting by linking it all back to how much that would be in milligrams of morphine.

Q And based on the research and your methodology that you explained to the Court, have MMEs declined to

the same extent as the prescription units that you discussed earlier since 2012?

A No, they have not. In 1999 -- or 1997, United States physicians were writing prescriptions that equated to approximately 100 morphine milligram equivalents per person. By 2007, that had increased to 700 morphine milligram equivalents per person. And by 2017, that had decreased to approximately 550 morphine milligram equivalents per person, still five times the amount of morphine prescribed -- or the amount of opioids prescribed in 1997.

Q Dr. Lembke, I want to turn to -- well, let me ask what's the significance of MMEs not declining to the -- at the same rate as the actual number of prescriptions?

A The significance there is that, in order to appreciate the extent of the increased prescribing, it's important not just to look at the numbers of prescriptions written per person but also how high those doses were.

One of the big shifts in terms of this paradigm shift was this idea that no dose is too high, that if a patient comes in saying that the analgesic effects have worn off, you can just go up on the dose and continue to go up and continue to go up with impunity and without increasing risk, which is how we got to the place where,

by 2007, we were prescribing 700 morphine milligram equivalents per person in the United States.

And just to put that into perspective, the average opioid-addicted person who gets methadone maintenance from a methadone maintenance clinic is on approximately 100 to 150 morphine milligram equivalents daily. So as a patient with pain seeing a doctor, you could get seven times the amount of effective opioids on a regular basis as you would get from a methadone maintenance clinic.

Q So, Dr. Lembke, I want to turn to the messaging around opioids, which was part of your opinions here.

You heard Dr. Perri testify about certain common promotional messages that were used by the four defendants in this case, correct?

A Yes, I did.

Q And have you reviewed substantially similar messages to those identified by Dr. Perri to determine whether those claims that are made in those messages are supported by the medical and scientific evidence and literature?

A Yes, I have.

Q And you did that as part of your research for your book and the work that you were doing prior to being retained as an expert by any government entity in opioid litigation, correct?

A Yes, I did.

Q And let me pull up the next slide.

Are these the misrepresentations that Dr. Perri identified and that you have seen in the promotional messages that you considered and analyzed in this case?

A These are the messages that I considered and analyzed, yes.

Q Okay. And what I want to do is go through each of those messages separately and talk about the scientific or medical evidence related to those messages. So if what we do is -- let's take the first one, which you've identified as misrepresentation number one, "Addiction to opioids prescribed for treatment of pain is rare."

A Yes.

Q Dr. Lembke, you testified a little bit earlier that about one in four people who are prescribed opioids will develop some form of OUD; is that correct?

A Yes, that's correct.

Q Okay. And can you explain -- can you elaborate on that a little bit more for the Court?

A Sure. The most robust resource for this to date is the Vowles, et al., article, showing that 21 to 29 percent of pain patients prescribed an opioid will misuse that opioid. And 8 to 12 percent of those individuals will develop a moderate to severe opioid use

disorder.

Vowles is a highly reliable source because it included a high number of studies, 38 studies; because it didn't use arbitrary quality measures but included multiple studies; and that, in fact, compared the aggregate results to the highest-quality studies and found that the highest-quality studies of the 38 studies had a consistent finding. The Vowles authors furthermore did not have any conflicts of interest.

Q Let me step back a little bit and just break this down. Rates of misuse averaged between 21 and 29 percent. What does rates of misuse represent here?

A So misuse in its simplest definition means using an opioid differently than how the doctor prescribed it. But in the Vowles study, their definition and measures of opioid misuse correspond very closely with the DSM criteria such that I believe that their opioid misuse category is consistent with mild opioid use disorder using the DSM-5 criteria.

And so -- sorry.

Q That's okay.

What is mild opioid use disorder?

A So the DSM-5 has 11 criteria to define and guide the diagnosis of opioid use disorder. And opioid use disorder is diagnosed on a spectrum, meaning that you can have a mild, moderate, or severe form depending upon how

many criteria are met.

So two to three criteria gives you a mild opioid use disorder, four to five is a moderate opioid use disorder, and six or more is a severe opioid use disorder, with some qualifications.

Q And, Dr. Lembke, can we go ahead -- can you identify for the Court the full title of the study that you were referring to here.

A Oh, at the bottom you see sources Vowles, et al., "Rates of Opioid Misuse, Abuse, and Addiction in Chronic Pain: A Systematic Review and Data Synthesis," published in 2015.

Q Where was this published?

A It was published in the journal Pain.

Q If you go up to this slide, "Across most calculations, rates of misuse average between 21 to 29 percent." And underneath it says, "Range, 95 percent confidence interval 13 to 38 percent."

Can you tell me what that means?

A That means that, although there's a range of results, we can be confident that the range occurs within -- that the true result occurs within that range.

Q So the true result occurs between 13 and 38 percent; is that right?

A Yes.

Q And then going on to rates of addiction average

between 8 and 12 percent.

Is that the severe OUD or moderate to severe OUD that you were talking about?

A Yes, it is.

Q And what is that confidence interval range?

A That means that we can -- with 95 percent surety, we can know that the true range is between 3 and 17 percent.

Q And you had identified -- tell us why you relied on this particular study for your conclusions concerning the rates of both mild OUD and moderate to severe OUD in pain patients.

A Again, because they included a large number of studies. 38 is a large number of studies for this subject in terms of a meta-analysis. The authors had no conflicts of interest --

THE COURT: Dr. Lembke, I did already hear your explanation. Thank you.

Ms. Fitzpatrick?

MS. FITZPATRICK: I want to turn to the next slide, Jon.

BY MS. FITZPATRICK:

Q Okay. And can you tell the Court what this slide represents.

A This slide is a timeline showing what was known when in terms of the rates of addiction to prescription

opioids among pain patients being prescribed opioids. And importantly what it shows is that, dating back as early as 1970s, there were studies showing that -- showing rates of as high as 24 percent of developing addiction in a pain population being treated with medicinal opioids.

You'll note that the second value is 0.03 percent, and that is the now infamous Porter and Jick study that was referenced by the industry to support the claim that the risk of addiction to opioids is rare or less than 1 percent in individuals who are getting prescribed opioids by a doctor. So that is not a reputable data point.

But even that aside, you'll see there's a broad range of findings here, but all the findings are well above the less than 1 percent that was attested to by the Porter and Jick. Furthermore, the Vowles article incorporates many of the studies listed here.

Q Now, turning to the next slide, what does the World Health Organization consider to be rare for an adverse event frequency in a pharmaceutical?

A The World Health Organization has provided this conceptual diagram for understanding when an adverse outcome is rare versus common. And as you can see, very common is greater than or equal to 1 in 10, common is greater than 1 in 100, et cetera, and very rare or rare

is less than 1 in 10,000 or greater than 1 in 10,000, less than 1,000.

The findings for the risk of addiction among chronic pain patients or pain patients being treated for opioids by any measure is not rare.

Q And does that include the 8 to 12 percent for the moderate to severe OUD?

A Yes. So that would -- that would suggest, then, that the true rate of becoming addicted to opioids when getting them from a doctor for a pain condition is common or very common.

Q And did you review some of the marketing and promotional claims by the defendants in this case concerning the rates of addiction to opioid medication?

A Yes, I did.

Q Okay. And I want to turn to the next slide. And these are documents that are already in evidence in this case.

Are these some of the examples that you picked that demonstrate a common message among the defendants in this case that addiction to opioids prescribed for treatment of pain is rare?

MS. FEINSTEIN: Objection, your Honor. The Fentora document referred to on this slide has not yet been entered into evidence. So I'll object on the basis of foundation and facts not in evidence.

MS. FITZPATRICK: Thank you.

Your Honor, that is my error.

Let's pull up 1367, Jon.

BY MS. FITZPATRICK:

Q Doctor, can you take a look at the document that's before you. And it will be in your Magna file too if you want to take a look at it in more detail. If you turn to second page, of this, Jon.

Do you recognize this document?

A Yes, I do.

Q And can you tell the Court what this document is?

A This is a document that was used internally to train sales representatives on Fentora.

MS. FITZPATRICK: Your Honor, I'm understanding there's no objection to the admission of this document. So the People will move P-CA-1367 into evidence at this time.

THE COURT: Any objection?

MS. FEINSTEIN: No objection, your Honor. Thank you.

THE COURT: P-1367 is admitted.

(Whereupon, Plaintiff's Exhibit No. 1367 was received in evidence.)

MS. FITZPATRICK: Jon, can you go back to the slide that we had up.

BY MS. FITZPATRICK:

Q And you do notice that the P-CA-1367 is in the top left-hand section of this slide. Can you explain to the Court what the four boxes on this slide represent?

A These represent false or misleading messages on the part of defendants that purported to claim that addiction to opioids prescribed for the treatment of pain is rare.

Q And why did you choose these examples?

A These examples were just emblematic of many of the documents that I reviewed.

Q And do you remember what the Kadian learning system is?

A Yes, I do.

Q All right. Can you tell the Court why you chose something from the Kadian learning system for this -- we lost the slide -- the Kadian learning system for an example here of what you call Misrepresentation Number 1?

A The Kadian learning system, like the Fentora "Introduction to Pain," was a document that was used internally to train sales reps, different from, for example, the "Finding Relief" document on this slide, which was a patient-facing document on the Duragesic website, which was a public-facing website.

I thought it was important to look not just at internal training documents but also to patient-facing

documents to explore the synchronicity or not between the messages that were being communicated to sales reps and to patient consumers and prescribers directly.

Q And what do you mean by "synchronicity"?

A To see what was being said to sales reps versus what was being said to prescribers and patient consumers. And what I found was that these false and misleading messages could be found in all of those places.

MS. FITZPATRICK: And if we turn to the next slide, Jon.

BY MS. FITZPATRICK:

Q And is this an example --

A I'm sorry. Do I have an opportunity to talk about those misleading messages?

Q We are going to. We'll go back to it, but I just wanted to identify this one as well.

Is this, the "Finding Relief Pain Management for Older Adults," is this something that you selected as well as an example of these what you call Misrepresentation Number 1?

A Yes.

Q Okay. And can you tell the Court what was significant about this document?

A Again, this was a patient-facing document that Janssen put together in collaboration with the American Geriatric Association. And I think what's striking here

is that the very myth that Janssen, in collaboration with the American Geriatric Association, acclaimed to be untrue are much closer to the truth than what they stated as fact. And I'm happy to go through them if you'd like.

Q I'd like you to start with the first myth, "Opioid medications are always addictive."

A Okay. So opioid medications are not always addictive, but they are often addictive. It is very common for patients to get addicted when exposed to a doctor's prescription. And it is simply not true that many studies show that opioids are rarely addictive when used properly for the management of chronic pain. Again I cited the Vowles study, which is the meta-analysis for that.

It states here as a myth that opioids make it harder to function normally --

Q Let me ask you a question about that. The Vowles study that we discussed, that was an analysis of multiple different studies that had been reported in the medical literature, correct?

A Yes. It was a meta-analysis.

Q And did any of those studies, independently and independent of the Vowles study, indicate that opioids are rarely addictive when using the World Health Organization standard for rare?

A Only the Porter and Jick, which is not a real

study. It was a letter to the editor based on a single-point observation of hospitalized patients, many of whom had received only a single dose of an opioid.

Q And do you consider the Porter and Jick letter to the editor to be a reliable source for basing what you have called evidence-based medicine?

A No.

Q And why not?

A As I said, it was based on a hospitalized population of individuals, many of whom were exposed to opioids only briefly, some with just a single dose. That can hardly be compared to outpatients receiving opioids at high dose for long duration.

Q And let's go to the second -- what is called here by Janssen a myth. "Opioids make it harder to function normally," and underneath it says "The Facts."

Can you explain to the Court whether that fact has basis in the medical and scientific literature?

A Yes. So this is important because it's a claim for increased function and improved function and improved quality of life on the part of Janssen, which is not supported by any evidence.

And, by the way, quality of life measures are very strictly considered in the scientific literature. It's not a claim that can be made easily by any pharmaceutical manufacturer.

And, in fact, opioids can make it harder to function normally. And, you know, for example, in my report I talk about workers' compensation data showing that individuals in California who went on medical leave for workers' compensation and received opioids for their injury or their pain were less likely to return to work than individuals who received no opioids for similar conditions.

Q And then the last myth here is that "Opioid doses have to get bigger over time because the body gets used to them." And underneath is "The Fact" that "Unless underlying cause of your pain gets worse, such as with cancer or arthritis, you will probably remain on the same dose or need only small increases over time."

Can you tell the Court whether there is support in the medical and scientific literature for that fact as identified in this "Finding Relief Pain Management for Older Adults"?

A Yes. So I think it's really important to understand that there is good evidence for the use of opioids in the treatment of pain short term. But the fundamental problem with using opioids daily over a longer period of time -- longer being more than 12 weeks, which is what we have definitionally used as the duration of chronic pain, that period of time after which normal tissue healing would have occurred -- that opioids

physiologically lose their ability to provide analgesia because of tolerance, which is why patients need to go up and up and up on their dose over time.

It is untrue to say that increasing the dose of the opioid over time is a result of the progression of the pain condition getting worse. That is potentially true, but the primary reason that opioid doses need to go up over time is because of the development of tolerance, which is almost universal.

Q And, Doctor, I want to go back to the slide before. And without reading these documents, which the Court has seen and which are in the record, can you explain the messaging that is contained in these examples that you chose for this slide?

A Yeah. So I want to start with the first one on the left that starts "like patients."

Your Honor, I think the keywords here are "Caregivers may need reassurance." This really speaks to the paradigm shift, the fact that prescribers were wary to use opioids for good reason, but that the opioid pharmaceutical industry reassured them against the evidence and against, frankly, common sense that they could use opioids. And they did so in part by making a distinction between what they called legitimate medical reasons or legitimate pain patients and individuals who are addicts, diverters getting drugs from the street.

Furthermore, I'll draw your attention to their saying that physical dependence to a drug is easily overcome through scheduling dosing decreases. There is nothing easy about getting an opioid-dependent patient off of opioids.

I am working with patients now who are on year three of their opioid taper. It is incredibly burdensome for them, for providers, for the healthcare system. And there is significant morbidity and mortality associated with dependence.

Q Dr. Lembke, if I can just make sure that the record is clear that what you're referring to here is excerpts from P-CA-1367 --

A Yes.

Q -- P-CA-001687, JAN-CA-602365, and P-CA-000251. Is that right?

A Yes, it is.

Q And focusing on the issue of whether addiction to opioid prescribed for the treatment of pain is rare, did you reach an opinion on whether the promotional messages that have been identified were false and misleading?

A Yes. I believe these promotional messages are false and misleading.

Q And in addition to the ones that you've identified on these two slides that we've identified in

the record, did you see examples of similar messaging related to risk of addiction from opioids in the other promotional material that you reviewed?

A Yes, I did.

Q And are they consistent messages across multiple promotional channels, I will call them?

MR. KABA: Objection, your Honor. Vague. Foundation.

THE COURT: On vague, it's sustained.

BY MS. FITZPATRICK:

Q Do you have an opinion, Dr. Lembke, as whether the statement that the risk of addiction was rare was a cause of more people being exposed to a larger supply of prescription opioids in California?

MR. KABA: Objection, your Honor. Lack of foundation.

MS. FEINSTEIN: Objection. Foundation.

THE COURT: On foundation, sustained.

BY MS. FITZPATRICK:

Q Dr. Lembke, have you offered testimony to the United States Congress on your research concerning these -- this type of marketing misrepresentation, or what you call a misrepresentation, that the risk of addiction was rare?

A Yes.

Q Okay. And have you offered -- have you been

invited to give testimony to the United States Congress on whether that statement or that marketing message was a cause of more people being exposed to a larger supply of prescription opioids?

MR. KABA: Objection, your Honor. Relevance.

THE COURT: Sustained.

MS. FITZPATRICK: Your Honor, I'm laying the foundation that this is part of the work that she has done and the research that she has done outside of this case.

THE COURT: That the same opinion is expressed somewhere else adds nothing to the foundation for the opinion. The objection is not to the witness potentially having said the same thing elsewhere but to the foundation for the opinion.

The objection to foundation is sustained. You may, of course, attempt to lay a foundation. And the foundation is not "I've said it before" or "I've said it often."

BY MS. FITZPATRICK:

Q Dr. Lembke, have you done independent research to determine whether there's a correlation between the statements -- the marketing message that the risk of addiction to opioids is rare and whether that was a cause of more people being exposed to a larger supply of prescription opioids? Have you done that research?

A Yes, I have.

Q And can you explain to the Court how you did that research?

A I looked at the medical literature and I looked at what the science actually showed about the risk of addiction in patients being treated with opioids for pain, and I compared that to the marketing messages to see whether or not those messages were consistent with the evidence in the literature.

And my conclusion was that those messages are not --

MR. BRODY: Your Honor, I'm sorry. I object to a statement of the conclusion. The question was simply whether -- how she did the research. I'd have a foundation objection.

THE COURT: The question as present is limited to what research was done to support an opinion.

BY MS. FITZPATRICK:

Q Dr. Lembke, before you get to the opinions, I don't want you to offer the opinions until the Court allows us to do so and if the Court allows us to do so. So I'm just asking you about the research that you did.

Is the type of research that you did into that question consistent with the way research is done in your field of expertise?

A Yes.

Q And can you explain that to the Court, please.
A To deeply explore the science and the medical literature and to come to a conclusion based on the weight of the evidence is a standard way to evaluate the literature.
Q And is that the type of research that you do in conjunction with your appointment at Stanford University?
A Yes, it is.
Q And earlier I think you said three legs on the stool of the position that you hold at Stanford University. Is that right?
A Um-hum, yes.
Q Is one of those research?
A Yes, it is.
Q And in conjunction with that appointment at Stanford and the research that you did, have you researched this particular question?
A Yes, I have.
Q And is the way that you've researched this particular question which you've described to the Court consistent with the way that medical and scientific research is done in your field of expertise and in conjunction with your appointment at Stanford University?
MR. KABA: Your Honor, I'm just going to object on vagueness grounds because at this point I don't know what this particular question is referring to.

THE COURT: Ms. Fitzpatrick, or directly to the witness, some confusion at the moment, certainly in my mind, is as follows: The witness, earlier on in the testimony, had a slide presented that contained a list of misrepresentations. Not purporting to identify all of them, but one was that addiction is rare; two was that opioid use disorder could just be pseudoaddiction; and so on.

The question at the moment is focused on the contention that to say that addiction is rare is a false and misleading statement.

Is the question whether the doctor isolated that one misrepresentation from the others and is expressing an opinion that that misrepresentation, that a standalone misrepresentation that addiction is rare, itself caused an increase in prescriptions? And if so, what's the basis for that opinion?

MS. FITZPATRICK: Your Honor, in the motions in limine there was no motion in limine that was raised as to whether Dr. Lembke could testify about whether these particular misrepresentations that we're going to go through were supported by the medical and scientific literature.

What I'd like to go through is, having established this misrepresentation as her opinion that it is false and misleading, is the effect of that type of

messaging on the medical community and on the prescribing behaviors of physicians.

THE COURT: Ms. Fitzpatrick, I understand that. My question is narrower. Is your question intended to elicit from Dr. Lembke that she investigated the issue of rareness -- that addiction is rare -- separate from the other causes or as one of the factors which, in her opinion, caused the increased writing of prescriptions?

MS. FITZPATRICK: The question is whether it's one of the factors, your Honor.

THE COURT: That's not how the question was framed. And if the doctor is answering it and purporting to lay her foundation, she needs to make clear whether she's laying a foundation for an opinion that a falsity about addiction being rare by itself caused an increase and, if so, what's the basis; or that it's one of the causes of the factors. And even then, precisely what she did to connect the dots between "I see false misrepresentations on the issue of it being rare and is causal, and the work I did to determine it was causal is as follows."

MS. FITZPATRICK: Thank you, your Honor. I think what we'll do is we will go through the misrepresentations, and then I will ask about the causal effect of the misrepresentations collectively at the end.

BY MS. FITZPATRICK:

Q Dr. Lembke, let me turn to the second misrepresentation.

If we could go back to that slide, Jon, Slide Number 5. Yes, Slide Number 6.

What did you identify as the second misrepresentation?

A That many patients exhibiting symptoms of opioid use disorder are suffering from pseudoaddiction.

Q Now, have you heard the term "pseudoaddiction" before your work in OUD and opioid addiction?

A I'm not sure I understand your question.

Q When did the term "pseudoaddiction" first appear in the medical literature?

A I'm not remembering exactly when it first appeared. It was in the context of a case report coauthored by David Haddox. This case report described an individual who was exhibiting signs and symptoms consistent with an opioid addiction who the authors of the report then determined that he, in fact, had what they call pseudoaddiction. He was in pain, and that the appropriate remedy was to simply go up on the dose.

So that was the only data point that introduced that term. It was not based, for example, on any kind of rigorous science. It was a made-up term in a case report.

Q And have you done an investigation to reach a

conclusion in this case as to whether there's a valid medical basis for the condition identified as pseudoaddiction?

A Yes. I've reviewed the literature on pseudoaddiction, and there is no valid scientific basis for pseudoaddiction. So this slide shows that that case report was published in 1989 by David Haddox. And also in --

Q If you can, we have to do it by question and answer, if you don't mind, Dr. Lembke.

Can you tell me about the 2018 study that you have identified as a basis for your opinions on this issue of pseudoaddiction?

A Yeah. So this was an article looking at the term "pseudoaddiction" in the medical literature and concluding that there was no empirical evidence to justify a diagnosis of pseudoaddiction.

Q And what was the recommended treatment for pseudoaddiction in patients who were prescribed opioids for pain?

A Right. So in the false and misleading messages, the implied and/or explicit recommendation for pseudoaddiction was to simply go up on the dose of opioids.

Q And --

MR. KABA: Objection, your Honor. Move to

strike, again foundation. And I'm just going to reassert my vagueness objection as to who are the individuals or entities with these messages?

THE COURT: Overruled.

BY MS. FITZPATRICK:

Q And turning to some of the promotional messages from the defendants in this case, did you look through the promotional messaging from these defendants in this case to find examples of the use of the term "pseudoaddiction"?

A I would phrase it a little differently. I would say I looked at promotional messages. And in the course of looking at their promotional material, I found frequent references to pseudoaddiction.

MS. FITZPATRICK: And if we can go to the next slide, Jon.

BY MS. FITZPATRICK:

Q And are these some of the examples that you found of the use of the term "pseudoaddiction" from these particular defendants in their promotional messaging?

A Yes, these are examples.

Q And each of those -- yeah, each of these documents is in evidence.

They are P-CA-399 and P-CA-251, for the record.

Can you tell the Court what the oxymorphone learning system is?

A The oxymorphone learning system was a document used internally to train sales representatives on how to think about and talk about these concepts with prescribers.

Q And what was the Kadian learning system?

A Similarly, the Kadian learning system was used to train sales reps on how to understand these concepts and how to communicate them to prescribers.

Q And why did you choose these examples from P-CA-399 and P-CA-251 for your testimony today?

A These were classic examples of how pseudoaddiction appeared in internal marketing material or training material.

Q Are these the only examples that you saw of the use of pseudoaddiction in marketing and promotional materials by these defendants?

A No. I've seen many examples in the many documents that I've reviewed that are consistent with these examples.

Q Okay. And in your opinion, are the marketing and promotional messages concerning patients exhibiting OUD symptoms suffering from pseudoaddiction false or misleading?

A Yes, they are false and misleading.

Q Can you tell us why?

A So pseudoaddiction is -- it's not -- it's not a

scientific concept; it's a made-up term. Furthermore, it in a very dangerous way contributed to making it more difficult for prescribers to detect and diagnose addiction in their patients who had become addicted to the opioids that they were prescribing. And it encouraged up-titration, increasing the dose of the opioid, which paradoxically increased that patient's risk of becoming further addicted to that opioid.

Q And I want to --

Can you go back to Slide Number 5, Jon.

Misrepresentation Number 3, the, quote-unquote, average person cannot get addicted to opioids prescribed by a doctor.

Can you -- based on your knowledge and expertise, can the average person who is prescribed opioids by their doctor get addicted to those opioids?

A Yes, the average person can get addicted through their doctor's prescription. Nearly anybody could get addicted through a doctor's prescription, given a high enough dose for a long enough duration.

Q And earlier today you talked about screening tools to identify patients who are at risk of developing OUD. Have you done research in the medical and scientific literature into those screening tools?

A Yes. As I've stated earlier, there are no valid or reliable screening tools to try to predict who will or

will not develop an opioid use disorder through a medical prescription. The opioid risk tool, which was championed by Lynn Webster, one of the key opinion leaders, had been shown to be no better than chance in figuring out who can and cannot -- who will and will not get addicted.

And although it is true that individuals bring varying levels of vulnerability to addiction through a doctor's prescription, we in the medical community have yet to discover a way to predict who those individuals are and the --

Q Let me just -- I don't mean to interrupt you, Doctor, but I just want to make sure that we've got a question and an answer for what we're doing here.

Jon, could you go to Slide 14.

So let me -- let me break this down a little bit. You just mentioned that prescreening for OUD risk is no better than chance. And I've put a slide up here. Are these the articles that you rely on for that particular opinion?

A Yes. So the one in the middle, the Clark, et al., rereviewed the opioid risk tool and found that it was no better than chance in predicting aberrant behavior in the course of medical treatment.

Q And it -- I don't mean to interrupt you, Doctor, but we need to do it in question-and-answer format.

That's Clark, et al., in Pain Medicine in 2018;

is that right?

A Yes.

Q And can you tell me the significance of the -- I think it's called Klimas; is that right? Am I pronouncing that one right?

A Yeah.

Q JAMA in 2019.

A Yeah. So Klimas, et al., did a more thorough look at screening tools and found that, really, there was no -- there were no high-quality studies demonstrating whether or not you could separate out high- from low-risk patients.

Q Okay. And I'd like you to talk about the Edlund article in Pain Medicine 2014.

Let me go back one slide to Slide Number 13, Jon.

Is this a graph from the Edlund article that you had referenced on the previous slide?

A Yes, it is.

Q And can you let the Court know what the source of this graphic is, please?

A This is Edlund, et al. The title is "The Role of Opioid Prescription in Incident Opioid Abuse and Dependence Among Individuals with Chronic Noncancer Pain," published in the Clinical Journal of Pain, 2014.

Q And can you explain to the Court what this slide

represents with respect to your opinions concerning whether the average person can get addicted to opioids prescribed by doctors?

A Yes. So Edlund, et al., took a very large population of patients and compared those exposed to a prescription opioid and those not exposed to a prescription opioid to figure out if and who would develop opioid use disorder and what the strength of that relationship was.

And what Edlund, et al., found was that individuals with no risk factors for opioid use disorder, like prior mental health disorder -- that's what you see here on the left-hand side of the screen -- or prior alcohol use disorder or prior mental health disorder, history or explicitly a prior opioid use disorder, were at increased risk to develop opioid addiction compared to those not exposed to an opioid.

But the very significant finding in Edlund, et al., is on the right-hand side of the study showing that, if you looked at risk of addiction as measured by how long the patient was on the prescription opioid and how high the dose was, that, importantly, for individuals prescribed an opioid for three months or more, the risk of developing addiction went up as a function of dose and that those who received, in the red bar, more than 120 milligrams per day were at 122 times the risk of

developing an opioid use disorder than individuals not exposed to an opioid.

Q Can you explain to the Court what a low dose and medium dose and a high dose is as used in this Edlund study?

A In that study a low dose was defined as 1 to 36 morphine milligram equivalents daily. The medium dose was defined as 36 to 120 morphine milligram equivalents daily, and a high dose was defined as anything greater than 120 morphine milligram equivalents daily.

Q Okay. And did you look at the promotional messages of the defendants related to assertions that the original person cannot get addicted to opioids prescribed by a doctor?

A Yes, I did.

Q And if we turn to Slide 15.

Does this slide represent some of the misrepresentations or some of the examples of the misrepresentations that the average person cannot get addicted to opioids through a doctor's prescription?

MS. FEINSTEIN: Objection, your Honor, to the extent that this slide includes messages from third parties. It lacks -- or it assumes facts not in evidence and lacks foundation as to any particular defendant.

THE COURT: Just a moment.

The objection is overruled.

BY MS. FITZPATRICK:

Q And, Doctor, the exhibits that are already in evidence that you reference on this slide are P-CA-1391, P-CA-251, and P-CA-399, correct?

A Yes.

Q And can you tell the Court why you chose these examples to demonstrate a common marketing message that the average person cannot get addicted to opioids through a doctor's prescription?

A These were simply illustrative of this false and misleading messaging. I'm trying to make this distinction between, quote-unquote, the average person or what was commonly referred to in these messages as a patient being treated for a legitimate pain condition and to somehow make a distinction between those individuals and so-called addicts or people who abuse drugs or people who divert drugs, when, in fact, those individuals, chronic pain patients and people who become addicted, can and often are one and the same.

Q And was the "American Pain Foundation: A Guide for People Living with Pain," was that a customer-facing material or an internal document?

A Yes, that was a patient consumer and prescriber consumer outwardly facing document.

Q And I think you testified that the learning systems were inwardly facing documents; is that right?

A That's right.

Q And did you see consistency among the external messaging as well as the messaging that was reflected internally concerning this misrepresentation?

A Yes, I did.

Q Okay. And did you see more examples in the promotional materials and the promotional messages from the defendants related to this Misrepresentation Number 3 that the average person cannot get addicted to opioids through a doctor's prescription?

MR. BRODY: Objection, your Honor; vague, and lacks foundation.

THE COURT: Sustained.

BY MS. FITZPATRICK:

Q The three documents here that you've represented here, are those just examples of common promotional messages that you have seen across --

THE COURT: Ms. Fitzpatrick, your voice has, for some reason, gone into a Star Wars routine is the only way I can describe it. Would you try that again?

MS. FITZPATRICK: Lucky you, Judge.

Is that better?

THE COURT: That is much better.

MS. FITZPATRICK: Okay.

THE COURT: You need to ask that question again.

BY MS. FITZPATRICK:

Q The three documents that you've identified here, are these examples of the common marketing message that you saw across the promotional materials that you reviewed in this case?

MR. KABA: Objection; foundation, vague, also leading.

THE COURT: The vague objection is sustained.

BY MS. FITZPATRICK:

Q Did you see other examples in the marketing promotional materials from the defendants of this Misrepresentation Number 3 that the average person cannot get addicted to opioids through a doctor's prescription?

MR. BRODY: Objection, your Honor; foundation, and vague as to "defendants."

THE COURT: Just a moment, please.

The vague objection is identified. The reference to other materials does not form the basis for any opinion and is simply going to lead to a distraction on cross-examination. Unless the doctor can identify them now, they should not be referred to.

MS. FITZPATRICK: Your Honor, would you like me to go through each of them? Some of the documents are already in evidence.

THE COURT: I don't know if the doctor can identify the other materials that you are referring to. You may ask.

BY MS. FITZPATRICK:

Q Dr. Lembke, did you look at the documents that were admitted into evidence in this case?

A Yes, I did.

Q And did you review the documents -- the defendants' own documents that were introduced into evidence in this case to see whether there were other examples of the Misrepresentation Number 3 that the average person cannot get addicted to opioids through a doctor's prescription?

A Yes, I did.

Q And did you see other examples of that in the documents that were introduced into evidence in this case?

MR. KABA: Your Honor, I'm going to object again on vagueness grounds. We don't know what the witness is referring to, and we have to compare what the witness is testifying to to what she actually disclosed in her report as well. And it's impossible to do that with this sort of question.

THE COURT: The vagueness objection is sustained.

MS. FITZPATRICK: Your Honor, I'm just pausing because I'm trying to think of the most efficient way to satisfy this without necessarily having to go through every single exhibit that's in evidence and identify it.

So I apologize for just pausing to think of the way that I can do this most efficiently.

BY MS. FITZPATRICK:

Q Dr. Lembke, in your opinion, are promotional messages that represent that the average person cannot get addicted to opioids through a doctor's prescription false or misleading?

A Yes, that is false and misleading.

Q And why is that false and misleading?

A The Edlund study shows that the biggest risk conferred is the dose and duration, not prior risk factors, which means that, number one, anybody on a high enough dose for a long enough period of time has a very high risk of becoming addicted.

Furthermore, the so-called average person that these misleading messages are referring to is set up as distinct from those individuals with, quote-unquote, addictive disease who engage in pharmacy theft, forged prescriptions, taking their pills from other people with pain, all of which sets up in a recipient's mind this false distinction between average people or legitimate pain patients and those drug addicts over there who are ruining it for the rest.

That's a false dichotomy. Anybody receiving an opioid from a doctor, even for the legitimate treatment of a medical condition, is at risk of becoming addicted.

And the biggest risk factors are not their personal history of addiction or mental illness but dose and duration as shown by Edlund.

I'd also, if I may speak individually to some of these misrepresentations, talk a little bit more about --

Q Dr. Lembke, if it's okay, I'm going to ask -- I know that you're used to lecturing, but I need to be able to ask you the questions just so the record is clear.

I do want to turn to the actual misrepresentations that you have identified on this particular slide. And if you can tell the Court why you selected these misrepresentations from the "American Pain Foundation: A Guide for People Living with Pain," which is P-CA-1391.

THE COURT: Ms. Fitzpatrick, the witness, each time you've shown her a slide like this, has confirmed that these are selected because they represent examples of where she believes the false and misleading statement appears. Do you want her to say something beyond that?

MS. FITZPATRICK: I wanted her to tell you, your Honor, why she selected these particular misrepresentations or these particular selections.

THE COURT: Dr. Lembke, anything you would add beyond what I just said?

THE WITNESS: Well, perhaps I've already communicated what I wanted to communicate to you, your

Honor. So perhaps there's no need.

I do think that the quote on the right-hand side at the bottom possibly requires some additional explanation, but perhaps not.

I guess I would say to you, your Honor, do you have any questions about these quotes and how they relate to the misrepresentation at the top?

THE COURT: I do not.

Ms. Fitzpatrick, do you have anything else on this slide?

MS. FITZPATRICK: No, I don't, your Honor.

Your Honor, I'm going to turn to another topic. Do you want me to keep going, given that it's the time --

THE COURT: No. If you're changing the subject, let's take a break at this time. We are adjourned until 3:10. Thank you.

(A brief recess is taken.)

THE COURT: Good afternoon, everybody. We are back on the record.

Ms. Fitzpatrick?

THE CLERK: Your Honor, your screen is yellow.

THE COURT: How about now?

THE CLERK: Okay.

MS. FITZPATRICK: I'm here, your Honor. Thank you. Sorry about that.

Jon, can we go back to Slide Number 5.

BY MS. FITZPATRICK:

Q Dr. Lembke, I want to talk about what you've termed Misrepresentation Number 4, "Opioids are an appropriate first-line, long-term treatment for chronic pain."

Let me start with some basic propositions.

What is chronic pain?

A Chronic pain is usually defined as pain persisting past the time that would be expected for normal tissue healing. By most definitions, chronic pain is pain that lasts most days for three months or more. There are some definitions in the literature using six months or more; but, in general, consensus has defined chronic pain as pain lasting three months or more.

Q And how does it differ from acute pain?

A Well, acute pain is pain of a short duration; so typically less than three months.

Q Okay. And why is that difference between chronic pain and acute pain significant when considering opioid therapies?

A Number one, the evidence does support the use of opioids short term in the treatment of acute pain. There is no reliable evidence that opioids work or are safe when used for more than approximately 12 weeks.

So that's -- that's a key -- a key piece.

Q And is there a difference between using opioids

long term to treat chronic pain and using opioids in the short term to treat chronic pain?

A Yeah. So that's an important distinction.

If you have a person who has chronic low back pain, for example, you've had that low back pain for three months or more, and you treat them with opioids, they will likely, if they tolerate the opioids, experience some relief.

But if you give that individual an opioid every day for more than three months, they will likely experience tolerance, dependence, maybe even interdose withdrawal. And there is no reliable evidence that the opioids are actually helping with their pain. In fact, in that instance, when patients take opioids, their subjective experience of pain relief is more likely treating their withdrawal from their last dose rather than the underlying pain condition.

Q You used a term in there, "interdose withdrawal." Can you tell the Court what that is?

A Because of this process of neuroadaptation to opioids and the tolerance that develops when people take them every day for more than three months, because they stopped working, patients will often report that they are indeed clock-watching, for example, because the analgesia has worn off before the time when they're supposed to take their next dose.

And once tolerance and interdose withdrawal occurs, that's a pretty good indication that that opioid at that dose is no longer helping the patient and may, in fact, be contributing to harm simply by the fact that now the patient is in this cycle of interdose withdrawal.

And I'll leave it at that.

Q Thank you.

If you can pull up, Jon, Slide 16. Let me see if I've got the right one. There it is.

And so, Doctor, can you explain to the Court what is represented on this slide entitled "Evidence of opioid benefits insufficient to justify the risks"?

A These are all articles in the medical literature which I have reviewed which I've included in my report, which represent important definitive studies of the benefits of opioids in the treatment of pain lasting longer than three months.

And in each instance, the authors concluded that the evidence was insufficient or weak to support the use of opioids in the treatment of -- to support the long-term use of opioids -- that is, opioids daily for more than 12 weeks, 12 to 16 weeks -- in the treatment of chronic pain.

Q And the studies that you chose are dated between 2009 and 2018; is that correct?

A Yes.

Q And can you tell -- point out to the Court a couple of the studies that you believed most establish -- or are consistent with your opinions here concerning the use of opioids long term to treat chronic pain?

A The first one by Chou, et al., is particularly significant because these were clinical guidelines for the use of chronic opioid therapy published in a definitive journal representing a definitive professional organization, the American Academy of Pain Medicine.

And their assessment that there was insufficient evidence to vet the effects on health outcomes was buried deep in the appendix of this article, when the earlier sections of this article actually strongly recommended the use of opioids in the treatment of chronic pain despite weak evidence. And --

Q And why did you consider the Chou article to be significant for your opinions in this matter?

A These were very influential guidelines on how physicians should be approaching opioid therapy and the treatment of chronic pain published in 2009. And most of the authors of this article, including the cochairs, were receiving consulting fees by defendants in this case and other opioid manufacturers.

Q So let's go to the next slide.

And does this reference the Chou article that you were just discussing?

A Yes, it does.

Q Okay. And tell me, what were the clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain that were advocated in this particular article?

A Well, as I said, this was a very influential article from an esteemed professional medical society, the American Academy of Pain Medicine, in conjunction with the American Pain Society, which put out these guidelines. And I think it's important to appreciate that doctors practicing in the modern age rely heavily on these definitive guidelines to inform them about what evidence-based care should look like.

MS. FITZPATRICK: And if we go to the next slide, Jon.

BY MS. FITZPATRICK:

Q This is entitled "Pain Guidelines Conflict of Interest." Dr. Lembke, can you tell the Court what this represents?

A So this has the authors of these guidelines, many of them on the left-hand side and, on the right-hand side, their conflicts and disclosures. And, as you'll see, many of them were receiving income from the defendants in this case.

The importance of this is that the influence that defendants exercised was very often in this manner

behind the scenes, supporting individuals and institutions that were promoting the expanded use of opioids in the absence of evidence.

And, as a result, the impact on physicians like me and my peers was to believe that this represented the best that science has to offer when, in fact, given these consultations -- or these consulting relationships, I think it's fair to argue that these individuals were -- were biased.

MR. KABA: Objection. Move to strike that last portion as lacking foundation with respect to the opinion on bias, your Honor.

THE COURT: No, the objection is overruled.

BY MS. FITZPATRICK:

Q And let's go back to slide -- let me ask you this: The pain guidelines conflict of interest, the cochairs, who among the defendants did -- have received fee income from -- excuse me. Let me start that all over again. It's getting late in the day for me.

Cochair, who among the defendants had provided a fee income to the cochairs of this clinical guideline?

A You can see that cochair Gilbert Fanciullo was receiving income from Janssen and Teva.

Q And Dr. Fine from Cephalon, Endo -- and Endo; is that right?

A Yes. That's right.

Q And as you go down this list, there are one, two, three, four, five, six, seven -- there are more than a dozen panel members who are identified here; is that right?

A That's right. The majority of the members were receiving some kind of funding from opioid pharma.

Q And that includes funding from Endo; is that right?

A That's correct.

Q Funding from Janssen?

A Yes.

Q Funding from Cephalon?

A Yes.

Q Funding from Teva?

A Yes.

Q And if we can go back to Slide Number 16.

Now, you have identified these clinical guidelines as recommending opioid therapy for Dr. Chou in 2009, but also indicate that there is lack of evidence.

Can you explain that to the Court?

A Well, I mean, it's -- it's difficult, in fact, to reconcile that the guidelines came out strongly in favor of using opioids in the treatment of chronic pain despite sufficient evidence supporting that recommendation. And, again, as I've just testified, I think that the fact that the majority authors were taking

funding from pharma would support bias in this case.

Q And you had testified earlier that you had done an analysis and research on the -- through the medical and scientific literature.

Did you look through that literature to determine the body of literature related to the evidence of opioids' benefits -- excuse me -- the evidence of the benefits of using opioids long term to treat chronic pain?

A Yes, I did.

Q Okay. And could you find evidence in that medical and scientific literature that supported the use of opioids long term to treat chronic pain?

A No, I could not find evidence to that effect.

Q And if opioids are not an effective long-term treatment option for chronic pain, what in your experience as a practitioner is an effective or an appropriate treatment option?

A Unfortunately, we do not have very good treatments for chronic pain. And the other treatments -- there are many other medications that are not opioids. There are many other interventions -- physical therapy, psychotherapy, other mind-body strategy -- and none of them have very good evidence.

Q And do any of those other treatment options that you have identified carry with them a risk of developing

addiction?

A Not that I'm aware, no.

Q And beyond the potential development of OUD and the ramifications of that, are there other dangers of using opioids as a first-line treatment for chronic pain in patients?

A There are many other side effects associated with long-term opioid use. Many people don't, in fact, tolerate opioids very well, whether long term or short term. Side effects include constipation, hormone changes, for example, lowered testosterone especially when used chronically. Cardiac effects are notable. People can develop problems with cognition, with depression.

There is, as I spoke of earlier, this phenomenon of opioid-induced hyperalgesia, showing that individuals who are on opioids long term actually can experience an exacerbation of their existing pain condition and/or develop pain in parts of their body where pain didn't even exist before.

Q Dr. Lembke, in your opinion, are messaging that assert that opioids are an appropriate first-line treatment for chronic pain false and misleading?

A Yes, on a number of counts. And as I said here several times, there is no evidence to support their effectiveness when used longer than about 12 weeks and a

mounting evidence of harm when used longer than 12 weeks.

And I think that the use of the term "first line" is also misleading. Opioids only in very rare instances should be first-line treatment for pain. And the reason for that, even in acute pain, is that exposure to opioids even in short term can set up vulnerable individuals to persist in using those opioids and developing addiction down the road.

Q Doctor, did you look through evidences in the record in this case to look for examples of this type of promotional messaging?

A I'm sorry. What type of promotional messaging?

Q That opioids are an appropriate first-line treatment for the treatment of chronic pain.

A Yes, I did.

Q Okay.

And I want to pull up first, Jon, P-CA-000421.

And, Doctor, do you recognize this document?

A Yes, I do.

Q And is this a document that you relied on for your opinions in this case?

A Yes, it is.

Q And is this a document that you relied on concerning marketing and promotional messages in this particular case?

A Yes, it is.

MS. FITZPATRICK: Your Honor, I believe there's no objection to the introduction of P-CA-421.

MR. KABA: No, that's -- that's not correct. We reserved objections pending the questions. At least as framed, we object on foundation grounds, your Honor.

THE COURT: Ms. Fitzpatrick, what's the question relating to the document?

MS. FITZPATRICK: I will go through -- it's going to be marketing messages in here, but if Mr. Kaba prefers, I can go through the marketing messages in order to identify them.

If we turn --

MR. KABA: Your Honor, if I may, the objection is as to foundation whether or not this witness can testify that this was used as marketing or promotion.

THE COURT: Ms. Fitzpatrick?

MS. FITZPATRICK: Your Honor, it's -- on its face, I don't think you need to be an expert to -- in marketing and promotion to know that, when you see a coupon savings card for an opioid product, that it is a marketing and promotional document.

I'm, again, candidly surprised. I understood that there was no objection to this document, and Dr. Lembke did use it and rely on it in her report as something that identified some of these common marketing and promotional themes that were seen throughout these

documents. And, for that reason, we would seek to admit it into evidence.

THE COURT: What is the stipulation, if any, regarding this document?

MS. FITZPATRICK: I'm looking at an e-mail that I got last night saying -- let me see -- that they are reserving a right to object to any questions that might be asked to any of these documents. But beyond that, there is no objection on hearsay and relevance, on foundation, on business record, or anything like that.

THE COURT: I don't know how to understand that e-mail. If all objections are reserved, what, if anything, is stipulated or agreed?

MS. FITZPATRICK: Your Honor, that there would be no objections that would be raised concerning hearsay, foundation, or that it was a business record.

THE COURT: Is that stated in the e-mail?

MS. FITZPATRICK: Yes.

THE COURT: Mr. Kaba, what is the foundation objection if there is no objection to foundation?

MR. KABA: Your Honor, that's not what the e-mail says. The e-mail -- I'm looking at it. It says we, of course, reserve our right to object to any questions that may be asked about any of these documents. With respect to this specific exhibit, we said we're reserving objections pending questions because we didn't

know what the witness was purporting the document to be.

The foundation objection, your Honor, is this witness is now being asked to opine that this was marketing and promotion communication. The only way it would be relevant is if it was in the plaintiff jurisdiction. There is no foundation for this witness to say that this document was used in the plaintiff jurisdiction as marketing or promotional messages. That's the foundation objection.

THE COURT: If there has been no stipulation to foundation, the foundation objection is sustained.

MS. FITZPATRICK: Thank you, your Honor.

Putting aside that -- can we just mark that for later? Okay. Thank you.

BY MS. FITZPATRICK:

Q Putting that aside, did you look at other examples of -- from the documents that are already in evidence in this case, as cited in your report, that opioids are an appropriate first-line treatment for the long-term treatment of chronic pain?

A Yes, I did.

Q Okay. And if we can turn to Slide 19.

Are these some of the examples that you selected that support Misrepresentation Number 4, "Opioids are an appropriate first-line treatment for long-term chronic pain"?

A Yes, they are.

MS. FITZPATRICK: And just for the record, we are reflecting Exhibit P-CA-1391, Exhibit P-CA-1693, AL-CA-300050, and JAN-CA-602365.

BY MS. FITZPATRICK:

Q And can you tell me why you chose these examples from the documents that are in evidence in this case as related to your opinions concerning Misrepresentation Number 4?

A Yes. And so these statements all allude in some way to using opioids long term in the treatment of pain, whether it's the first one, "They may be important to the management of persistent pain unrelated to cancer," which again supports this idea of expanded use beyond malignant end-of-life pain.

The second one, key feature message, this is important because it refers to an article in the literature which was 12 weeks in duration, by Katz, et al. And this article was then used and prompted for sales reps to use with prescribers in a broader statement about using opioids to treat pain long term, i.e., chronic pain.

Kadian sales rep training one uses this "first line" language, when, in fact, opioids, very dangerous drug, should not be used first line, and that's supported by the CDC guidelines that came out in 2016.

And then the "Finding Relief," that's the patient-facing document that Janssen -- implying that people being treated with opioids for chronic pain can return to a normal existence and find that they will use it long term to somehow get the life back that they had when there's no evidence to support that.

MS. FITZPATRICK: Go back to Slide Number 5 again, Jon.

BY MS. FITZPATRICK:

Q Let's turn to misrepresentation -- what you called Misrepresentation Number 5, "No dose of opioids for the treatment of pain is too high."

Doctor, in your review of the medical and scientific literature, is there evidence to support the proposition that no dose of opioids for the treatment of pain is too high?

A No. There's -- there's no evidence to support that, and there is evidence to support the opposite.

Q Okay.

Please go to Slide 20, Jon.

Does this slide reflect some of the support that you have for your opinion that no dose of opioids for the treatment of pain too high is a false message?

A Yes. So this shows the odds ratio or the risk of overdose in individuals treated with different amounts of opioids for chronic pain. There's a group of patients

receiving no opioids, less than 20 morphine milligram equivalents, 20 to 50, 50 to 100, and then greater than 100 and looking at their risk of overdose as a function of the dose that they are receiving. It's showing that the higher the dose the higher the risk of opioid overdose.

And this is Dunn, et al., at the bottom, but these -- these findings have been replicated in other studies -- the Gomes article, Bonnard, et al. -- showing very similar findings.

Q For the record, this is Dunn, et al., "Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study." Is that right?

A That's right.

Q And when was that published?

A 2010.

Q And where was that published?

A In the Annals of Internal Medicine.

Q Is that a reputable journal?

A Yes, it is.

Q Is there a relationship between exposure to opioids and the potential of overdose and deaths?

A Yes. That's what this slide is showing, that the higher the exposure, the higher risk of opioid overdose and death.

Q And are promotional messages that state or

suggest that no dose of opioids for the treatment of pain too high, do you have an opinion as to whether that is a false or misleading message?

A Yes. I believe that to be false and misleading.

Q Do you have any other reason than what we've just discussed with the Court?

A To believe that that's false and misleading?

Q Yes.

A Not right now.

Q Okay. And did you look through the documents that are in evidence in this case to determine whether there are -- to look for examples of this type of promotional messaging related to no dose of opioids for the treatment of chronic pain is too high for the defendants in this case?

A Yes, I did.

MS. FITZPATRICK: Okay. We can turn to Slide 21, Jon.

And just for the record, this slide reflects P-CA-1391, P-CA-401, P-CA-579, P-CA-625, P-CA-251.

BY MS. FITZPATRICK:

Q And can you tell the Court why you selected these examples from documents that are in evidence that are related to your opinions concerning the marketing message that no dose of opioids for the treatment of pain is too high?

A So the first on the left from the American Pain Foundation uses language that was common in these false and misleading messages, namely that no ceiling dose exists.

It's important to clarify that, pharmacologically, opioids do not have a ceiling dose. A ceiling dose is defined as finding the receptor and continuing to stimulate the receptor as the amount of the opioid goes up.

But it's misleading here to use a pharmacologic term to talk about how the drug works at the cellular level to communicate that that is true in a clinical setting when, in fact, there's evidence showing that the higher the dose the higher the morbidity and mortality.

Also, this juxtaposition of opioids with NSAIDs, or nonsteroidal anti-inflammatory, was a common misleading strategy to get providers who do struggle with the side effects of NSAIDs, putting their patients at higher doses in particular, mainly GI side effects -- ulcers, bleeding dyscrasia. But to juxtapose that with NSAIDs was a way to promote opioids saying how you can't keep going up on NSAIDs or, for that matter, Tylenol because of the liver damage that Tylenol can cause, but opioids you can keep going up and up.

And then other misleading messages in the statement. I can run through the others if you like.

Q No. I just wanted to reflect it for the record if there's anything specific in here that you need to draw the judge's attention to that requires your specialized skill or knowledge to explain. Otherwise, we will move on.

A The only thing that I would point your Honor's attention to is the frequent use of "tolerance." For example, in the Endo quote, which is second -- it's in the middle on the left-hand side -- it says, "If tolerance does occur, it does not mean that you will run out of pain relief."

Your Honor, that's exactly what tolerance means. It means that you will run out of pain relief. And you've got one of two options then. You've got to go up on the dose, or you've got to get off.

Q And, Doctor, just so I'm clear, are these examples of the type of promotional messages that you believe are false or misleading?

A Yes, these are examples. And I think this idea of "no dose is too high" represents a particularly insidious false and misleading message among my peer group of physicians. We -- I was the recipient of these messages, and I, with my peers, truly believed at one point that we could just go up and up and up on the dose and our patients wouldn't be harmed. And, as a result, we have an entire generation of patients who are on

extremely high, extremely dangerous doses and now struggling to get off.

MS. FEINSTEIN: Excuse me. Objection, your Honor, to the last response and move to strike the end of that answer as unfounded hearsay as to her colleagues and the causation is an improper opinion without foundation.

THE COURT: Just a moment.

Everything after the first sentence in the answer was nonresponsive to the question and is stricken.

BY MS. FITZPATRICK:

Q And let's turn to Misrepresentation Number 6, "Physiologic opioid dependence is benign and easily reversible."

Did you look at that misrepresentation to see whether it's supported in the medical and scientific literature?

A Yes, I did.

Q So let's start with what is physiologic opioid dependence?

A Physiologic opioid dependence is the process of neuroadaptation to the presence of the opioid, resulting in downregulation of dopamine and our own endogenous or internal production of our own opioids to accommodate the external or exogenous influx of opioids, leading to a condition where, if that individual were to lower their dose of opioids or stopped abruptly, they would venture

into the classic syndrome of opioid withdrawal.

Q And is there support in the medical and scientific literature for the proposition that, once a patient develops physiologic opioid dependence, it is benign and it is easily reversible?

A No. In fact, there's a growing body of work showing that, for patients who become physiologic -- physiologically dependent on opioids, especially chronic pain patients, that lowering their dose or getting off altogether is extremely difficult.

MS. FITZPATRICK: If we can turn to Slide 22, Jon.

BY MS. FITZPATRICK:

Q And does this slide, entitled "Dependence is a Serious Condition and Hard to Treat," summarize your findings from your review of the medical and scientific literature concerning whether opioid dependence is benign and easily reversible?

A Yes. So these are a series of studies that undertook trying to taper opioid-dependent chronic pain patients who, importantly, did not meet the five criteria for opioid use disorder but were -- merely met criteria for physiologic dependence and struggled to get off.

So, for example, the Weimer study was a study showing tremendous effort on the part of a large clinic to help these individuals taper down and finding that it

was extremely difficult to do so.

And, by the way, these were individuals in whom it had already been determined that the risks of continuing on opioids outweighed any potential benefits. In other words, they were deemed to not be experiencing benefit from continuing opioids and were experiencing harms.

Q Dr. Lembke, can you tell the Court what breakthrough pain is?

A Breakthrough pain is a phenomenon of patients who have become tolerant to and dependent on opioids who then experience pain in the midst of a period of time when that opioid should be managing or covering their pain. So breakthrough pain is, in essence, an example of the development of tolerance to the analgesic effects of opioid.

Q And going back to your clinical experience and the work that you've done, the BRAVO protocol that you previously identified, is that related to this topic of whether or not opioid dependence is benign and easily reversible?

A Yes. The BRAVO protocol was developed in recognition that tapering chronic pain patients who are physically dependent on opioids to lower doses is difficult to do. And it requires a certain amount of expertise. It requires time. It requires extensive

health services. It requires the patient to endure quite a bit of pain and suffering.

So the BRAVO protocol was a way to help support healthcare providers in helping patients taper when the risks of continuing outweighed any potential benefit. And the BRAVO protocol -- sorry -- just one more thing I want to add -- you know, does review the evidence of risks versus benefits.

And the Frank, et al., article here, which is the second-to-last bullet point, speaks to a growing number of studies showing that when these patients do taper to lower doses or off of opioids, many of them experience improvement in pain. So their pain actually gets better or it gets no worse.

Q And has that been something that you have seen in your clinical experience in treating patients who have opioid dependence?

A Yes, it is.

Q And in addition to the medical and scientific literature that you cite here for the proposition that opioid dependence can be a difficult condition to treat, is that also something that you see in your clinical practice in treating patients who have opioid dependence?

A Yes. A growing number of patients in our clinic expressly come to us for help with opioid tapering in the context of opioid dependence. These are typically not

patients who meet criterion for opioid use disorder. They are patients with chronic pain who have been taking opioids for years exactly as prescribed by their doctor.

Q And I want to go through -- back to this issue of breakthrough pain. And if you can turn to Slide 23.

And you've identified here documents in evidence as P-CA-1303, the 2005 document entitled "Actiq Marketing Plan."

What is the relevance of P-CA-1303 to your opinions here concerning breakthrough pain?

A I think it's important to make the distinction that in somebody on hospice care who has 12 weeks to live, and we're trying to relieve their agony at the end of life and we give them opioids and they experience breakthrough pain, in that context that it would very much make sense to give them additional opioids on top of that to ease their suffering because the amount of time they have to live makes the issue of developing addiction for that matter, you know, overdose irrelevant.

But in the context of treating chronic pain, this notion of breakthrough pain, I think, has a very deleterious effect because it then encouraged providers to pile one opioid on top of another.

We were encouraged to have long-acting opioid and then to prescribe additionally short-acting opioids to be taken for, quote-unquote, breakthrough pain. If

there was breakthrough through the short-acting opioids, we were encouraged to prescribe fast-acting opioids to immediately target breakthrough pain using things like transmucosal fentanyl products to squash the breakthrough pain.

But the result of all of that, ultimately, is that the patient ends up on higher and higher doses, develops more tolerance to those doses, which then requires higher doses of both the long-acting agent and the short-acting agent for breakthrough pain, increasing their risk of overdose and addiction.

Q And, Dr. Lembke, can you tell me, are there risks to a patient while undergoing treatment for OUD or opioid dependence?

A I'm not sure I understand your question.

Q Let me -- let me try it again.

Do patients who are undergoing treatment for OUD, medically assisted treatment for OUD and dependence, do those treatments present unique risks or independent risks to patients?

A Okay. So the pharmacologic therapies that we have for opioid use disorder consist of three medications: buprenorphine, commonly referred to as Suboxone; methadone maintenance provided in liquid form through a methadone maintenance clinic; and naltrexone, which is an opioid receptor blocker.

So just focusing on the first two, buprenorphine -- both methadone and buprenorphine are unique opioids in that they have a very long half life. And the reason why that's helpful in the treatment of opioid use disorder is because it gets individuals out of this cycle of intoxication, withdrawal, and drug seeking, which takes so much of their energy and creativity, and it achieves this steady state.

Also buprenorphine has some additional features that make it safer than other opioids. It is less likely to cause respiratory suppression or respiratory depression than other opioids, making it less likely to result in accidental overdose, although it too can contribute to accidental overdose, especially in combination with other competing agents.

Q Dr. Lembke, in your opinion, are marketing messages that suggest that opioid dependence is benign and easily reversible false and misleading?

A Yes.

Q And did you go through some of the documents that are in evidence in this case to find examples of promotional messaging that suggests that opioid dependence is benign and easily reversible?

A Yes, I did.

Q If we can go to Slide 24, Jon.

Doctor -- do you want to take a quick break,

Doctor?

A No. I'm okay.

Q Okay. I just wanted to make sure.

What's up on the slide are document references P-CA-1391, P-CA-399, and P-CA-251.

Are those examples of the Misrepresentation Number 6, that is, "Physiological opioid dependence is benign and easily reversible"?

A Yes, they are.

Q Okay. Can you explain to the Court why you chose these three documents as examples of that marketing messaging?

A Yes.

So on the left-hand side, both of those messages equate the physical dependence from opioids to dependence that occurs to other medications. Although it is true that patients can habituate to blood pressure medications like beta blockers, it's misleading to equate the severity and morbidity associated with opioid dependence and opioid withdrawal to that experienced when people habituate to things like beta blockers.

Q Can I just clarify that what you're talking about on the left-hand side are references to P-CA-1391 and P-CA-399?

A Yes. Right.

And then the other important thing here is

there's lots of misleading messaging that talks about dependence and tolerance and withdrawal not having anything to do with addiction. It's making this very stark distinction between opioid use disorder and physical dependence when, in fact, of the 11 criterion the DSM-5 used to diagnose opioid use disorder, two of those criteria are tolerance and withdrawal.

And these phenomena are linked. They are not distinct phenomena.

Q And, Doctor, I want to turn now to something that I believe you referenced earlier today, which was the gateway effect. Can you explain to the Court what the term -- what you mean by gateway effect?

MR. BRODY: Objection, your Honor; cumulative of Dr. Stafford and Dr. Quick.

THE COURT: Ms. Fitzpatrick, what would be different or additional about this?

MS. FITZPATRICK: Your Honor, I'm just laying -- truly in just a -- not too many questions -- of Dr. Lembke's understanding of the gateway effect. And I'm going to tie it together with laying a foundation later and asking her ultimate opinions in this case about the cause and effect.

THE COURT: I have not previously raised the issue, nor have counsel, that the doctor has been asked numerous questions that others have defined.

Breakthrough pain is one example. Chronic pain is another example. The definition of opioid is another example.

Cumulatively, these repetitive questions do take up inordinate amounts of time. Unless it is essential to redefine gateway effect, please just ask your questions.

BY MS. FITZPATRICK:

Q Doctor, I'm just going to ask you just a couple of questions here without going into too much detail.

Have you done research and looked at whether both medical and nonmedical use of prescription opioids can be gateways to heroin use?

A Yes, I have.

Q And do you, based on the research that you have done in this case, and your experience in treating those who suffer from OUD and opioid dependence, believe that both medical and nonmedical use of prescription opioids can be gateways to heroin use?

MR. BRODY: Same objection, your Honor; cumulative of Dr. Quick and Dr. Stafford.

THE COURT: Overruled.

THE WITNESS: Yes, I believe that the weight of the evidence shows that exposure to prescription opioids, whether obtained medically or nonmedically and used medically or nonmedically, increases that individual's risk of using heroin at a later date.

BY MS. FITZPATRICK:

Q Dr. Lembke, I want to ask you some opinions in this case. And I can do that since it's a bench trial. I'm just going to ask you a series of questions, not what your opinion is but to what's called lay the foundation for the opinions. So just whether you have opinions or not. Okay?

A Okay.

Q I don't want to run afoul of any of the Court orders.

Earlier today you testified that prior to the 1990s, there was a conservative consensus against the use of prescription opioids for the treatment of chronic pain, correct?

A Yes.

Q And as part of your professional research work at Stanford in the areas of prescription opioids and their use, have you investigated the rates in opioid prescribing from the 1990s to the present?

A Yes.

Q And you testified about those increased rates earlier today, correct?

A Yes.

Q And as part of your professional work at Stanford in the area of prescription opioids and OUD, have you investigated what -- any of the potential causes

of this increased rates of opioid prescribing from the 1990s to the present?

A Yes, I have.

Q And did you attempt, in doing that work, to investigate factors that may have -- all factors that may have contributed to this change in the conservative consensus?

A Yes, I did.

Q And in doing this investigation, did you review medical and scientific literature?

MR. KABA: Objection; leading.

THE COURT: Overruled.

THE WITNESS: Yes, I did.

BY MS. FITZPATRICK:

Q And how did you go about selecting or reviewing medical and scientific literature in order to reach your opinions?

A I used search words to collect articles from the literature. I specifically looked for articles that had differences of opinion so as to not leave out any perspective.

I looked at consensus statements from learned bodies like the National Academies of Sciences, Engineering, and Medicine and what they had concluded from similar types of literature searches.

I compared my reading of the literature with the

documents provided by defendants in this case as well as incorporated my own qualitative research, interviews I had done with healthcare providers and patients.

Q Let me -- let me break this down, Dr. Lembke. I just want to make sure that we're doing this.

So I had asked you about the medical and scientific literature that you had researched. Was your method of going about obtaining and reviewing that medical, scientific literature when you were investigating the factors that may have contributed to the change in the conservative consensus -- was that consistent with the research techniques that you regularly utilize in your position at Stanford University?

A Yes, it was. And I've included everything that I reviewed in the materials considered, which is more than 600 articles.

Q And is the methodology that you used to review that medical and scientific -- to both obtain and to review that medical and scientific literature -- is that consistent with the way that research is done in your field?

A Yes, that's a standard academic approach to understanding the medical science.

Q Okay. And in addition to your review of, I think, over 600 medical and scientific -- well, first of

all, let me ask this: The medical and scientific literature that you reviewed and you relied on, did you identify that in your expert report in this case?

A Yes, I did.

Q And have you also used that medical and scientific literature for other academic publications by you outside of an expert report in this case?

A Yes, I have.

Q And what academic publications are those?

A I and colleagues published an analysis of a 2013 Medicare database looking at what types of doctors are prescribing opioids and found that opioid prescribing is not --

Q I'm going to ask you to hold off on what the actual opinions are. Doctor, I'm just asking you the methodology for how you got there, if that's okay.

A Okay. So we analyzed Medicare Part D 2013 database. I've also published articles on the appropriate perioperative use of buprenorphine, analyzing the literature and taking expert consensus opinion. I've published articles looking at the use generally of opioid agonist therapy perioperatively in patients with opioid use disorder.

I've published articles -- and, again, this is all with collaborators and colleagues -- looking at weighing the risks, benefits, and alternatives of the use

of opioids in the treatment of chronic pain to deeply understand what the evidence actually shows.

Q And, Doctor, I want to focus on the particular issue of the factors that you investigated to determine -- or to reach opinions on what contributed to the change from the conservative consensus in the 19 -- prior to the 1990s, to the more liberal use of opioids in the 2000s and beyond. Okay?

So focusing on that particular opinion, have you reviewed the literature -- the medical and scientific literature that you identified in your report here for the support of those opinions? Have you also published that -- those opinions and that work elsewhere relying on the same literature?

A Yes.

Q And where did you publish your research outside of your expert opinion in this case -- or your expert report in this case?

A Looking at that narrower question of how opioid messaging impacted physician prescribing, my major contribution to that literature is my book based on qualitative interviews that I've done.

Q And what other information did you rely on besides the medical and scientific literature to reach your opinions on whether opioid messaging impacted physician prescribing?

A Well, I looked at, you know, specific empirical studies in this literature. I also looked at consensus reports. For example, the May 2017 report in the literature.

I then compared what I found there to the misleading messaging to try and see whether or not that messaging was, in fact, informed by the science.

Q And going beyond whether the messaging was actually informed by the science, what did you do to determine whether that marketing -- those marketing messages had an actual impact on access to or availability of opioids?

A Um-hum.

Well, I think, first and foremost, again, I interviewed stakeholders in the medical community to find out what their exposure was to any marketing and messaging material on opioids and how it impacted their prescribing. And I also related it to my own personal experience, having been the recipient of this messaging in its heyday, and how -- how I was impacted by that messaging as well as my clinical experience of seeing patients being prescribed opioids from their doctors and the impact that it had on those individuals.

Q And is that an accepted methodology in your field to reach conclusions to answer the question of whether the messaging material concerning opioids

impacted prescribing of opioids?

A Yes, it is.

Q And you have mentioned in there how -- your own personal experience of having been a recipient of this messaging. Can you tell us what your own personal experience having been a recipient of this messaging was?

A Yes. I will say when I graduated from medical school, I had received minimal training in addiction and also minimal training in the treatment of pain. Very limited hours dedicated to either of those subjects.

And then in my early career -- well, in my residency, I was exposed to a gradual and iterative paradigm shift that was influenced by messages like pain is undertreated because physicians are opioidphobic and we are, in fact, harming patients because we are withholding opioids.

I remember when the Joint Commission came to my hospital and told us that pain is the fifth vital sign and that we should screen every patient for pain and that, if we were not doing that and doing, quote-unquote, everything in our power to target their pain, then we were remiss and, in fact, violating to some extent their right to pain treatment.

And I also, again, through my entire early career starting in the late 1990s to approximately 2010, was repeatedly inundated with the message that, as long

as I, the physician, am prescribing to a patient with a bona fide and legitimate pain condition, their chances of getting addicted to the opioid that I was prescribing were so small as to be discounted, negligible, not an area of concern.

Q And, Doctor, going beyond your own personal experience --

THE COURT: Ms. Fitzpatrick, just before you ask the question, would you take the slide down since it dominates the screen?

MS. FITZPATRICK: I'm so sorry, your Honor.

THE COURT: Thank you.

BY MS. FITZPATRICK:

Q Okay. And, Doctor, going beyond your own personal experience, did you reach opinions in this case as to whether the marketing misrepresentations that you identified, the six misrepresentations, influenced or were a cause of increased prescribing of opioids?

A Yes. I believe that the false and misleading --

MR. BRODY: I'm sorry, your Honor. The question was simply whether she had reached opinions. I object on foundation grounds to the expression of those opinions.

THE COURT: At this stage the question just calls for a yes or a no.

THE WITNESS: Can you restate the question, please.

BY MS. FITZPATRICK:

Q Doctor, going beyond your own personal experience, did you reach opinions in this case as to whether the marketing misrepresentations that you identified, the six misrepresentations that we discussed, were -- caused an increased prescribing of opioids by physicians?

A Yes, I did reach an opinion about that.

Q And what is that opinion?

MR. BRODY: I object, your Honor; lack of foundation.

THE COURT: Overruled.

MR. KABA: Your Honor, I would also join in that objection and note that the witness testified -- when the witness was testifying as to foundation, or the attempt to lay foundation, one of the first things she said was she interviewed stakeholders in the medical community to find out about exposure to marketing and messaging. That is hearsay.

And insofar as it's driving an opinion with respect to the plaintiff-specific jurisdiction, it's case-specific hearsay for which no exception applies.

So I would add a hearsay objection on top of the foundation objection.

THE COURT: The objection is overruled.

BY MS. FITZPATRICK:

Q And, Dr. Lembke, what is your opinion?

A My opinion is that the false and misleading messages on the part of the defendants was a significant factor in opioid overprescribing and the development of the opioid epidemic.

MS. FITZPATRICK: Your Honor, we have nothing further.

THE COURT: Dr. Lembke, as is apparent, you will need to come back. I think rather than have examination start at this hour, I'm going to adjourn at this time. The defendants will begin their cross-examination at 9:00 a.m.

Now that the examination has concluded, under the rules applicable to this trial, you are not allowed to discuss your testimony with the People's counsel. Please take that seriously.

THE WITNESS: Yes, I will, your Honor.

THE COURT: We are adjourned until 9:00 a.m. tomorrow morning. Thank you.

MS. FITZPATRICK: Thank you, your Honor.

(Conclusion of proceedings at 4:14 p.m.)

REPORTER'S CERTIFICATE

I, Carolyn Gregor, CSR NO. 2351, approved court reporter pro tempore, do hereby certify that the foregoing Reporter's Transcript; consisting of pages through 2523, is a full, true and correct transcription of my shorthand notes thereof, and a full, true and correct statement of the proceedings had in said cause, taken via Zoom, to the best of my ability.

Dated at Newport Beach, California, this 18th day of May, 2021.

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CAROLYN GREGOR, CSR 2351, CRR, CM, RDR

COURT APPROVED REPORTER PRO TEMPORE

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